Zutron Medical Enteroscope & Fujinon DBE Stiffening Device
ZUTR142000 / ZUTR162000
Information for Use

The Enteroscope Stiffening Device (ESD) is a reusable one-piece device. It consists of a handle and a stiffening wire that is tapered and more flexible at the tip.

Attention: Read all instructions prior to use.

Notes:

- Caution: Federal Law restricts this device to sale by or on order of a physician.
- Do not use device for purposes for which it is not intended.
- The coordination of endoscope channel size with compatible devices is essential in order to get optimal results and to prevent injury to scope or patient.
- Carefully remove wire from package by pulling it out slowly by handle.
- Dispose of packaging. DO NOT store wire in package

Indications for Use:

- For the Fujinon DBE retrograde procedure when added scope stiffness is desired to negotiate a difficult colon or advanced proximally into the ileum.
- To assist enteroscopy when scope looping prevents advancement down the small intestine.

Instructions for Use – Retrograde for Fujinon DBE procedure

1. To provide added scope stiffness to assist in advancement to the cecum and into the ileum.
2. Once the entry into the transverse colon is confirmed, withdraw scope to straighten out scope and biopsy channel.
3. Prior to each use, inspect ESD to confirm handle is secure and wire smooth.
4. Gently advance ESD down the entire length of the biopsy channel.
5. Advance scope to cecum and into ileum.
6. Withdraw the ESD at the physician's discretion. The EDS may be left inserted, partially withdrawn, or fully withdrawn depending on the segment of the scope requiring stiffness. (Leaving ESD inserted may aid in straightening the ileum and advancement of enteroscope).
7. Always use gentle advancement techniques and don't force a maneuver.
8. Upon completion of procedure, follow institution's policy for reprocessing.

Instructions for Use – Enteroscopy

1. Use when enteroscope looping creates difficulty in negotiating the stomach or small intestine.
2. Prior to each use, inspect ESD to confirm handle is secure and wire smooth.
3. Gently advance ESD down the desired length of the biopsy channel. Position within the channel in the area corresponding to the segment of scope that requires additional stiffness or straightening.
4. Using the described double-balloon technique, advance the scope down the small intestine to the ileum.
5. The physician at his discretion, will decide when to best use the ESD to aid in advancing to the ileum by adding scope stiffness to reduce looping and assist with the telescoping maneuvers of small bowel endoscopy.
6. Withdraw the ESD at the physician's discretion. The EDS may be left inserted, partially withdrawn, or fully withdrawn depending on the segment of the scope requiring stiffness.
7. Always use gentle advancement techniques and don't force a maneuver
8. Upon completion of procedure, follow institution's policy for reprocessing.

Warnings:

- This device must be inspected before and after each use for possible damage to the surface of the device, such as indentations, or cracks, caused by trauma to the device from sharp edges. Use of the device after the surface integrity has been compromised may lead to the device breaking at the point of damage.
- Discard damaged device. Kinked or bent device cannot be safely straightened.
- Should an ESD break during a procedure, care should be taken not to dislodge the wire by insertion of another accessory into the biopsy port. Instead withdraw the endoscope from the patient and straighten, allowing the wire to fall out of the distal end
- Not intended for use prior to entering the transverse colon
- Do not use in enteroscopes with an insertion tube shorter than 200 centimeters
- The ESD should never be extended beyond the bending section of the endoscope

Precautions:

- Protective eyewear and other personal protective equipment must be worn according to institution policy whenever removing wire from package or uncoiling wire. Wire has a memory and will straighten out very quickly.
- Device should only be used by or under supervision of a physician thoroughly trained in endoscopic procedures.
- Never force device through scope channel.

Reprocessing and Storage:

- Reprocess according to your institution's reprocessing policy.
- Immediately following the procedure, wipe the shaft and the handle of the wire with enzymatic solution. Use caution as to not sharply kink or bend the tapered end.
- Do not coil in smaller than a 9" diameter.
- Store by hanging vertically on a hook in a clean dry area.

Zut-Lab-002-2000 Rev J

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Zutron Medical Stiffening Device
ZUTR141700 / ZUTR161700 / ZUTR14200 / ZUTR16200
High Level Disinfection Instructions

These instructions are applicable to reprocessing of the Zutron Medical Stiffening Devices, including all model numbers listed above.

These reusable devices are considered to be a Class II device or non-critical (items can come in contact with skin but not mucous membranes), which is a low risk device only requiring high level of disinfection as recommended by C.D.C., SGNA, A.A.M.I. & APIC Standards & Practice.

WARNING
Used devices should be considered as contaminated & appropriate handling precautions should be taken during reprocessing. Appropriate hand washing and gloves, gown, eye protection & mask should be worn.

DECONTAMINATION

- Device should be cleaned in a sink reserved for this purpose.
- Wipe down device under running water.
- Check device for any rough areas. Entire device should be smooth & free of kinks or barbs.
- Immerse instrument in an approved enzymatic solution mixed per manufacturer's recommendation. Re-wipe total surfaces, brush out hole in handle, and soak for time period recommended by enzymatic manufacturer.
- Rinse instrument with clean tap water & wipe down with dry cloth.

HIGH LEVEL DISINFECTION (HLD)

- Coil in no smaller than a 9" diameter coil & place device into HLD solution, following label directions as to time & temperature.
- Automated Endoscope Re-processors are encouraged. Coil in no smaller than a 9" diameter coil and place in the tray prior to putting in the endoscope.
- Rinse device with clean water.
- Wipe down device with alcohol soaked cloth or 4X4 gauze.
- Dry exterior and re-inspect device for damage.
- Store by hanging device in vertical position in a clean, dry storage area.

STERILIZATION

- Place device in dedicated trays or packages/pouches suitable for desired sterilization process.
- Take extra precautions while coiling device.

Sterilization Method	**Temp**	**Minimum Exposure Time - Wrapped**
PRE-VACUUM	270° – 275° F	4 minutes
GRAVITY	250° – 254° F	15 minutes
	270° – 275° F	10 minutes
ETHYLENE OXIDE (EtO)	125° – 130° F	105 minutes with 12% EO - 88% FREON
		45 – 75% chamber humidity, aeration of 6 hours

NOTE:
It is the responsibility of the re-processor to ensure the reprocessing has actually occurred properly. This may require validation and monitoring of process.

Instruments returned to Zutron Medical must have a statement that testifies the device has been thoroughly cleaned and disinfected.