SWICKER SPONGE

Radiopaque Surgical Foam Sponge

Instructions for Use

DESCRIPTION:

SWICKER is a sterile foam sponge designed for single-patient use. **SWICKER** is a highly absorbent surgical sponge intended for use in a variety of surgical or medical procedures. **SWICKER** can be used in multiple surgical procedures and areas including patient prepping, open surgery, laparoscopic, and robotic surgery, instrument padding, instrument cleaning, and wound care.

SWICKER is packaged dry and can be used dry or hydrated. **SWICKER** is extremely soft, strong, and flexible, and is well-suited for delivery through a laparoscopic trocar (refer to table1 for trocar sizes). It resists tearing and is cellulose free. See below for **SWICKER** hydrating process.

SWICKER is sufficiently durable and tested to be used continuously during the same procedure and can be temporarily left in place during the surgery. Suction can be applied to clear the **SWICKER** or wrung out and used continuously during the same procedure. **SWICKER** contains radiopaque ink marker dots that are applied to the sponge. **SWICKER** is available in multiple sizes and thicknesses (refer to Table 1).

INDICATIONS:

SWICKER is a sterile, single-use device indicated for use as a surgical sponge substitute. It can be used to protect soft tissues under surgical retractors and has significant strength and integrity to be used as a retraction device. It can be pushed through and retrieved through a laparoscopic trocar using a grasper with teeth. See Table 1 for **SWICKER** sizes and corresponding Trocar sizes.

CONTRAINDICATIONS:

None known.

INSTRUCTIONS FOR USE:

1. Using aseptic techniques, peel open package and transfer **SWICKER** to the sterile field/personnel.
2. **SWICKER** can be used dry for packing or for drying and cleaning a medical device.
3. To hydrate the **SWICKER,** submerge it and squeeze it a few times until it becomes completely saturated in sterile bowl of sterile fluids.
4. Fold up or roll up to wring out excess solution into a trash receptacle prior to use.
5. **SWICKER** can be cleaned and reused continuously throughout the procedure by either wringing the blood or body fluids out in a bowl or by using suction to clear the sponge.
6. Wring out excess fluid prior to disposal. Dispose of contaminated devices in accordance with hospital policy and regulations for disposal of biohazard medical waste. Non-contaminated, unused devices may be disposed of per hospital guidelines.

PRECAUTIONS:

1. **SWICKER** should be stored in its original sealed package at room temperature, away from direct sources of heat.

WARNINGS

1. Do not use **SWICKER** past the expiration date indicated on the label.
2. Do not use **SWICKER** if the sealed pouch is punctured, torn, or otherwise compromised.
3. Do not use **SWICKER** if the device is visibly torn, frayed, or damaged.
4. Do not re-sterilize. **SWICKER** is supplied sterile and is intended for single patient use only.
5. Do not leave **SWICKER** inside the body. It must be removed after use.

Table 1: **SWICKER** Radiopaque Foam Sponge Sizes

Config.	**SWICKER Size** (Inches)			**Allowable Trocar Size** (mm)
	Width	**Length**	**Thickness**	
-201	0.50	3.00	0.125	≥5
-202	1.00	3.00	0.125	≥5
-203	1.50	3.00	0.125	≥5
-205	3.00	3.00	0.125	*
-207	5.00	5.00	0.125	*
-209	9.00	9.00	0.125	*
-301	0.50	3.00	0.250	≥5
-302	1.00	3.00	0.250	≥5
-303	1.50	3.00	0.250	≥10
-305	3.00	3.00	0.250	*
-307	5.00	5.00	0.250	*
-309	9.00	9.00	0.250	*
-401	0.50	3.00	0.500	≥5
-402	1.00	3.00	0.500	≥10
-403	1.50	3.00	0.500	≥12
-405	3.00	3.00	0.500	*
-407	5.00	5.00	0.500	*
-409	9.00	9.00	0.500	*

* = Not to be used with Laparoscopic trocars

Table 2: Symbol Glossary

Symbol	Title (Reference)	Description
	Manufacturer (5.1.1[1])	Indicates the medical device manufacturer
	Use-by date (5.1.4[1])	Indicates the date after which the medical device is not to be used
	Batch code (5.1.5[1])	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number (5.1.6[1])	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Sterilized using ethylene oxide (5.2.3[1])	Indicates a medical device that has been sterilized using ethylene oxide
	Do not resterilize (5.2.6[1])	Indicates a medical device that is not to be resterilized
	Do not use if package is damaged and consult instructions for use (5.2.8[1])	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Do not re-use (5.4.2[1])	Indicates a medical device that is intended for one single use only.
	Consult Instructions for Use (5.4.3[1])	Indicates the need for the user to consult the instructions for use
	Single sterile barrier system (5.2.11[1])	Indicates a single sterile barrier system
	Single sterile barrier system with protective packaging outside (5.2.14[1])	Indicates a single sterile barrier system with protective packaging outside
	Unique Device Identifier (5.7.10[1])	Indicates a carrier that contains unique device identifier information
	Prescription only (21 CFR 801.109)	Caution: Federal law restricts this device to sale by or on the order of a physician

[1] ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.