

TECHNICAL DATA SHEET



PRODUCT

Sure-Check™ Sterilization Pouches

PRODUCT OVERVIEW

Sure-Check Sterilization Pouches feature internal/external multi-variable indicator technology that confirms all three CDC sterilization criteria of time, temperature, and pressure in the form of steam as compared to traditional sterilization pouches with a single parameter indicator monitoring only temperature. Meets CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

The Crosstex Sure-Check Sterilization Self-Seal Sterilization Pouches have been validated to be double pouched and processed in the following conditions and operating cycles:

- Dynamic air removal (Pre-vacuum and SFPP) steam sterilization cycle of 270 °F (132 °C) for 4 min. exposure.
- Gravity steam sterilization cycle of 270 °F (132 °C) for 15 min. exposure.

MATERIALS

Paper – 60 gsm Medical Grade Paper (55%)

Plastic – 2 mL Polyester Cast Polypropylene (45%) (Clear)

Adhesive Tape – ½ mil polyester film coated sides with 1.4 mils of high tack, shear acrylic adhesive that exhibits good temperature resistance.

Indicators - Internal/External printed directly on pouch. Contain lead carbonate and sulfur.

DETAILS

- Internal/External Multi-Variable Indicators – only change color when all three criteria for sterilization have been met: time, temperature, and pressure in the form of steam
- Secure Seal – extra wide chevron seal protects against instrument breaching
- Medical Grade Paper – wet strength treated, virgin medical grade kraft paper that meets medical pouch standards
- Transparent Film – allows a clear view of the contents as well as the internal indicators
- Wide Self-Seal Adhesive Strip – securely seals pouch and provides sterilization integrity of contents during storage; contents will remain sterile for three years provided the integrity of the pouch is not compromised.
- Perforated Fold – allows for accurate folding of adhesive strip to form an airtight seal, maintaining the integrity of the pouch during storage after sterilization
- Complete Paper-Film Separation – high quality of materials and manufacturing process assures a consistently clean separation (peeling) of the film from the paper, maintaining the sterile integrity of the contents
- Thumb Notch – assures easy opening of pouch
- Corner Tack Seals – three tack seals on each corner prevent curling and possible separation after sterilization; prevents the collection of dust and other contaminants in the sealed area

STORAGE REQUIREMENTS

Room temperature (10-38°C) and 30-60% humidity. In addition, you should avoid storage conditions that could contribute to the contamination of a product (i.e. bioburden, air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap material).

SHELF LIFE

Prior to sterilization: 3 years from date of manufacture.

Post sterilization: when properly sealed, sterility is maintained up the three (3) years provided the integrity of the pouch has not been compromised, i.e. pouch becomes wet, damaged or is opened during storage. Please refer to AAMI ST79 Section 11.1.3 Shelf Life, additionally, follow your facility policy on sterility maintenance.

PACKAGING

Product is available in the following configurations

Product Code	Description
SCXX2	2.25"x4"/6x10cm Sure-Check™ Sterilization Pouches - 200/Box
SCX2	2.75"x9"/7x23cm Sure-Check Sterilization Pouches - 200/Box
SCXS2	3.5"x5.25"/9x13cm Sure-Check Sterilization Pouches - 200/Box
SCS2	3.5"x9"/9x23cm Sure-Check Sterilization Pouches - 200/Box
SCS25	3.5"x9"/9x23cm Sure-Check Sterilization Pouches - 500/Box
SCL3222	3.5"x22"/9x56cm Sure-Check Sterilization Pouches - 100/Box
SCW2	5.25"x6.5"/13x17cm Sure-Check Sterilization Pouches - 200/Box
SCM2	5.25"x10"/13x25cm Sure-Check Sterilization Pouches - 200/Box
SCL5152	5.25"x15"/13x38cm Sure-Check Sterilization Pouches - 200/Box
SCL2	7.5"x13"/19x33cm Sure-Check Sterilization Pouches - 200/Box
SCL8162	8"x16"/20x41cm Sure-Check Sterilization Pouches - 200/Box
SCL10152	10"x15"/25x38cm Sure-Check Sterilization Pouches - 100/Box
SCL10172	10.5"x17"/27x43cm Sure-Check Sterilization Pouches - 100/Box
SCL12152	12"x15"/30x38cm Sure-Check Sterilization Pouches - 100/Box
SCL12182	12"x18"/30x46cm Sure-Check Sterilization Pouches - 100/Box

SINGLE-USE DESIGNATION

Sterilization pouches are single use only items. Do not re-use.

PLEASE NOTE: Sure-Check Sterilization Self-Sealing Pouches are not considered hazardous waste and can be disposed of in regular trash (40 CFR 261.24 tested using the TCLP, EPA Publication SW-846).

REGULATORY INFORMATION

US FDA 510K#: K941327
 Regulation: 880.6850
 Regulation Name: Sterilization wrap
 Regulatory Class: Class II
 Product Code: KCT
 Medical Device Listing: E646228
 Compliant with ISO 11140-1 Type 4 and 11607 standards