

TECHNICAL DATA SHEET



<u>PRODUCT</u>	Duo-Check™ Sterilization Pouches
<u>PRODUCT OVERVIEW</u>	<p>Duo-Check Sterilization Pouch internal and external process indicators (Type 1 Process Chemical indicators) change color with sterilization heat and are compatible with steam and EtO sterilization agents. The Crosstex Duo-Check Sterilization Self-Seal Sterilization Pouches have been validated to be double pouched and processed in the following conditions and operating cycles:</p> <ul style="list-style-type: none"> • 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.
<u>MATERIALS</u>	<p>Paper – 60 gram medical Kraft paper (55%)</p> <p>Plastic – 2 mL Polyester Cast Polypropylene (45%) (blue)</p> <p>Adhesive Tape – ½ mil polyester film coated sides with 1.4 mils of high tack, shear acrylic adhesive that exhibits good temperature resistance</p> <p>Indicators - Internal/External printed directly on pouch. Contain lead carbonate and sulfur</p>
<u>DETAILS</u>	<ul style="list-style-type: none"> • Secure Seal – extra wide chevron seal protects against instrument breaching • Medical Grade Paper – wet strength treated, virgin medical grade paper that meets or exceeds medical pouch standards • Blue Tinted Transparent Film – facilitates both easy instrument viewing and identification of punctures or tears in film • Wide Self-Seal Adhesive Strip – easily and securely seals pouch, providing reliable seal until pouch is opened • Perforated Fold – facilitates easy, accurate folding of adhesive strip to form airtight seal until pouch is opened • Complete Paper-Film Separation – consistently clean separation (peeling) of paper and film due to high grade materials and adhesives • Thumb Notch – assures easy opening of pouch • Six Corner Tack Seals – prevents corners from curling after sterilization and tacks resist collection of dust and contaminants near seal • Type 1 Process Chemical Indicator Arrows – change color with sterilization heat, are easily visible, and are compatible with steam and EtO sterilization agents
<u>STORAGE REQUIREMENTS</u>	<p>Room temperature 50-100°F (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).</p>

PACKAGING

Product is available in the following configurations

Product Code	Description
SCZ	2"x8"/5x20cm Duo-Check™ Sterilization Pouches – 200/Box
SCXX	2.25"x4"/6x10cm Duo-Check Sterilization Pouches - 200/Box
SCX	2.75"x9"/7x23cm Duo-Check Sterilization Pouches - 200/Box
SCQ	3.25"x9"/8x23cm Duo-Check Sterilization Pouches - 200/Box
SCXS	3.5"x5.25"/9x13cm Duo-Check Sterilization Pouches - 200/Box
SCS	3.5"x9"/9x23cm Duo-Check Sterilization Pouches - 200/Box
SCL322	3.5"x22"/9x56cm Duo-Check Sterilization Pouches - 100/Box
SCB1X	4.25"x11"/11x28cm Duo-Check Sterilization Pouches - 200/Box
SCM	5.25"x10"/13x25cm Duo-Check Sterilization Pouches - 200/Box
SCL515	5.25"x15"/13x38cm Duo-Check Sterilization Pouches - 200/Box
SCL	7.5"x13"/19x33cm Duo-Check Sterilization Pouches - 200/Box
SCL816	8"x16"/20x41cm Duo-Check Sterilization Pouches - 200/Box
SCSPP	3.5"x9"/9x23cm Duo-Check Sterilization Pouches (Pink Film) - 200/Box
SCMPP	5.25"x10"/13x25cm Duo-Check Sterilization Pouches (Pink Film) - 100/Box
SCS5	3.5"x9"/9x23cm Duo-Check Sterilization Pouches - 500/Box
SCL1015	10"x15"/25x38cm Duo-Check Sterilization Pouches - 100/Box
SCL1215	12"x15"/30x38cm Duo-Check Sterilization Pouches – 100/Box
SCL1218	12"x18"/30x46cm Duo-Check Sterilization Pouches – 100/Box

SINGLE-USE DESIGNATION

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

PLEASE NOTE: Duo-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).

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.

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 1 and 11607 standards

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