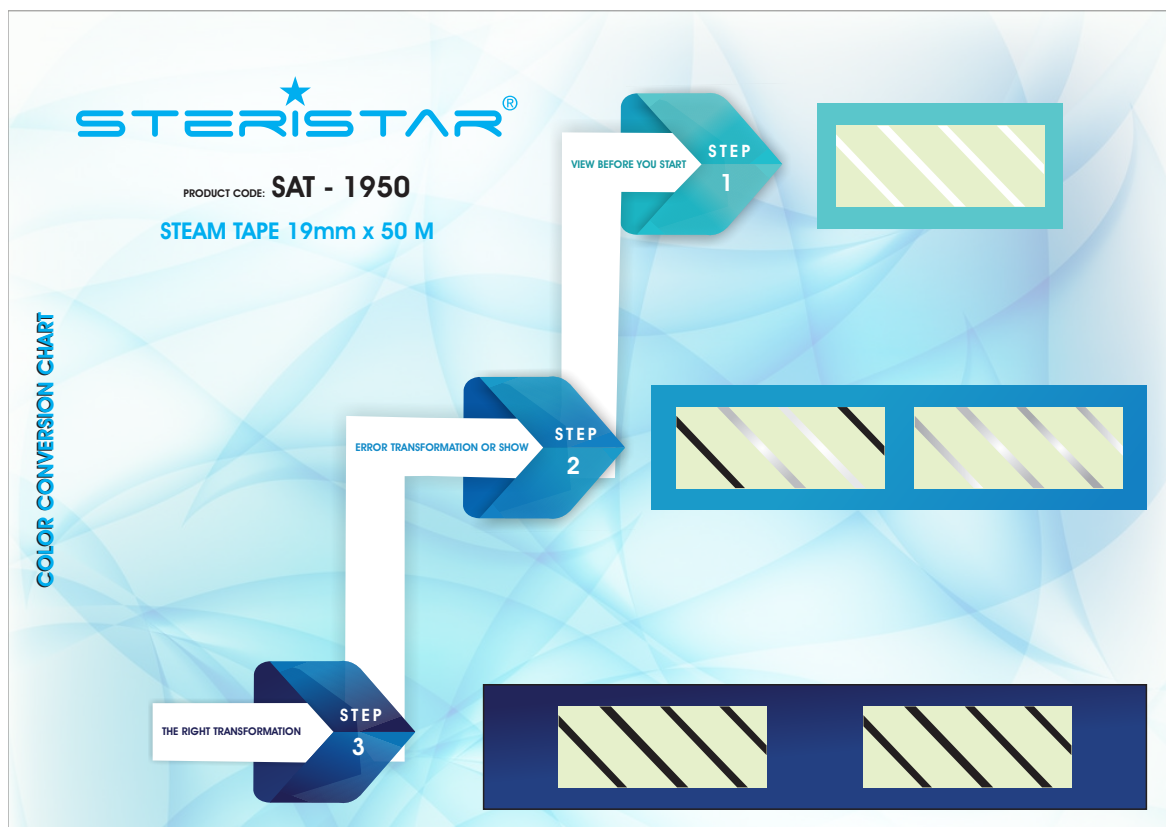


38.4 pirkimo dalis. Cheminis indikatorius - juosta

Spalvos pasikeitimas



prieš

klaida

po

STERISTAR®

PRODUCT CODE: E - 1950

EO TAPE 19mm x 50 M

COLOR CONVERSION CHART

VIEW BEFORE YOU START

STEP
1



ERROR TRANSFORMATION OR SHOW

STEP
2



THE RIGHT TRANSFORMATION

STEP
3



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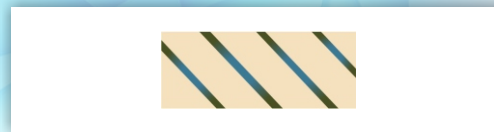
VIEW BEFORE YOU START

STEP
1



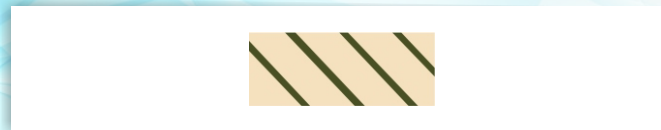
ERROR TRANSFORMATION OR SHOW

STEP
2



THE RIGHT TRANSFORMATION

STEP
3





Sterilization Steam Tape

Ref Codes:

SAT-1950 (19mm X 50M)

SAT-2550 (25mm X 50M)

Product Description

A reliable sterilization tape that provides immediate identification of processed items and also serves as a closure tape to seal sterilization packs. Chemical indicator strips change color when exposed to appropriate sterilization conditions.

Sterilization tape changes color when subjected to steam sterilization process. It is important to note that the presence of sterilization tape that has changed color on an item does not ensure that the product is sterile, the tape only shows if sterilization has been performed.

Physical Parameters

Process	Steam
Dimensions	19mm X 50M or 25mm X 50M
Packaging	1 pcs. / pack
Chemical Indicator	Initial color: White, Signal color: Dark brown / Black %100 Toxic Heavy Metals Free
Adhesive	Tape remained adherent on the surface after the right sterilization process
Composition	Crepe Paper, Single layer.



Chemical Composition	The sterilization indicator used in printing is water based and contains following components in ppm levels.
	Lithium carbonate %15 -20 (CAS#554-13-2)
	Triethylamine %1-5 (CAS#121-44-8)
	Normal Propanol %1-5 (CAS#71-23-8)

	SPECIFICATION	UNIT	STANDARD	TYPICAL VALUE
AUTOCLAVE TAPE	WIDTH	mm	-	19±1
				25±1
	LENGTH	m	-	50± % 1
	THICKNESS	micron	-	110±10
	ADHESIVE	g/m ²	-	28±3
	INSTANT TACK	N/25 mm	ASTM D3121	350±50
	PEEL ADHESION	g/25 mm	ASTM D3121	450±80
	INDICATOR CONTROL	-	ISO 11140-1	Must return the specified color

Intended Use

The tapes are for use in all Steam sterilization processes.

- 134 °C 3,5 min. – 120 °C 15 min.

Instructions for Use

STERISTAR lead free steam indicator tape for steam sterilization consists of an adhesive, backing, and chemical indicator stripes. The adhesive is an aggressive, pressure-sensitive adhesive designed to adhere to a variety of wraps, including untreated woven (i.e., reusable % 100 cotton and cotton and poly blends) and disposable non-woven, paper and paper/plastic wraps in order to secure the pack during steam sterilization. After sterilization, the tape is designed to remove easily and cleanly from untreated woven wraps. The backing is a beige colored crepe paper and provides the stretch needed for pack expansion during sterilization. The chemical indicator lines will show a visual color change from white to dark when exposed to a steam sterilization process.

1. Remove the poly packaging and install tape roll in a compatible tape dispenser.
2. Unwind a section of indicator tape long enough to secure the pack.

Vidinis juostos paviršius lipnus, išoriniame paviršiuje – cheminių dažų linijos, kurios garų poveikyje keičia spalvą. Juosta turi būti ypač stiprios fiksacijos, ritinėlio šonai nelipnūs, nepritraukia nešvarumų, klėjai netepa rankų. Sterilizacijos metu nenukrenta, o po jos lengvai nuimama.

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3. Place one end of the indicator tape on the package and apply finger pressure across the length of the tape to secure the pack. Please do not stretch the tape across the pack as it may cause bundle popping.
4. Repeat steps 2 and 3 if the method of the package wrapping or pack size requires two strips of indicator tape.
5. After steam sterilization, the chemical indicator lines will show a visual color change from white to dark.
6. When the pack is ready to use, open by tearing the tape at the pack's point of opening (at the point of the fold flap). Do not remove tape from wraps in the operating room to guard against linting.
7. Remove tape section from reusable woven wraps prior to laundry procedures. When applying tape to reusable woven wraps it is recommended to fold over and end of each strip of tape to create a tab to facilitate easy removal before laundering.

Process the packages/items as instructed in the sterilizer validation or manual. Upon exposure, the indicator will transition from white to dark brown/black. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from white to a shade of dark brown/black provides indication of exposure. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 1 minute. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met.

Performance Characteristics

Results Availability:	Immediately following exposure to Steam processes.
Unexposed*	Exposed to 134°C 3,5 min. – 121 °C 15 min. *
	



*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.



The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a steam Process Indicator, any color change produced during exposure to steam which is close to signal color is considered acceptable.

Compliance

ISO 11140-1:2014

ISO 13485:2016

ISO 11607-1:2014

Storage and Shelf Life

	Do not reuse		Keep dry
	4°C to 30°C		Keep away from sunlight
	10% - 40% RH		Shelf life 2 years from the date of manufacture



Keep away from sterilants.

Do not use damaged Indicators or Indicators which have transitioned to black.
Do not use after expiration date.

Do not expose this product to Dry Heat, EO, H2O2 or any sterilization processes
other than Steam.

Disposal

Discard as general waste.



Necati KAYA
TIBBİ CİHAZLAR İTHALAT VE İHRACAT
SANAYİ VE TİCARET LİMİTED ŞİRKETİ



REF:SAT1950-SAT2550

Lead Free Indicator Tape for Steam Sterilization

DIRECTIONS FOR USE

INDICATION FOR USE

STERISTAR lead free indicator tape for steam sterilization consists of an adhesive, backing, and chemical indicator stripes. The adhesive is an aggressive, pressure-sensitive adhesive designed to adhere to a variety of wraps, including untreated woven (i.e., reusable % 100 cotton and cotton and poly blends) and disposable non-woven, paper and paper/plastic wraps in order to secure the pack during steam sterilization. After sterilization, the tape is designed to remove easily and cleanly from untreated woven wraps. The backing is a beige colored crepe paper and provides the stretch needed for pack expansion during sterilization. The chemical indicator lines will show a visual color change from blue to dark when exposed to a steam sterilization process. STERISTAR Steam Tape is a Type I Process Indicator as categorized by ISO 11140-1:2014.

This products is made by latex free materials.

COLOR CHANGE

The indicator color change from blue to dark when exposed to a steam sterilization cycle.

DIRECTIONS FOR USE

1. Remove the poly packaging and install tape roll in a compatible tape dispenser.
2. Unwind a section of indicator tape long enough to secure the pack.
3. Place one end of the indicator tape on the package and apply finger pressure across the length of the tape to secure the pack. Please do not stretch the tape across the pack as it may cause bundle popping.
4. Repeat steps 2 and 3 if the method of the package wrapping or pack size requires two strips of indicator tape.
5. After steam sterilization, the chemical indicator lines will show a visual color change from blue to dark.
6. When the pack is ready to use, open by tearing the tape at the pack's point of opening (at the point of the fold flap). Do not remove tape from wraps in the operating room to guard against linting.
7. Remove tape section from reusable woven wraps prior to laundry procedures. When applying tape to reusable woven wraps it is recommended to fold over and end of each strip of tape to create a tab to facilitate easy removal before laundering.

STORAGE

- Storage at normal room temperature 15 °C - 30°C and 10-70% RH
- Store exposed indicator away from light sources
- Do not store near strong alkaline or acidic products such as cleaning / disinfecting agents. Store away chemicals and sterilants (e.g. hydrogen peroxide)
- After use the indicator will not change visually within 6 months when stored at above conditions



EXPIRE DATE

The expiry date is printed on the product packaging. Do not use after expiration date listed on the packs.

LOT NUMBER

Unique identification code, LOT is printed on each indicator and packaging labels.

INTERFERING SUBSTANCES OR CONDITIONS

There are no know interfering substances or conditions that could affect the intended use of the indicator or adversely affect the indicator performance.

RELEASE OF TOXIC SUBSTANCES

The indicator releases no know toxic substances in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.



REF: SAT1950-SAT2550

Lipni bešvinė juosta su garų indikatoriumi

NAUDOJIMO INSTRUKCIJA

STERISTAR bešvinė juosta su garų indikatoriumi yra iš vienos pusės lipni, su indikatoriaus brūkšniais. Kljai yra stiprios fiksacijos, todėl juosta tinkama naudoti kartu su įvairiomis pakavimo medžiagomis, įskaitant neaustinį pluoštą ir popierių. Po sterilizacijos juosta pašalinama lengvai ir be likučių. Juostos pagrindas yra pagamintas iš rusvai gelsvo krepinio popieriaus ir turi tamprumo, reikalingo pakavimui. Paveikti sterilizacijos garais proceso cheminio indikatoriaus brūkšniai pakeičia spalvą iš mėlynos į tamsią. STERISTAR juosta su garų indikatoriumi yra klasifikuojama kaip 1 klasės proceso indikatorius, remiantis ISO 11140-1:2014.

Šis produktas yra gaminamas be latekso.

SPALVOS PASIKEITIMAS

Sterilizacijos garais metu indikatoriaus spalva iš mėlynos pasikeičia į tamsią.

NAUDOJIMAS

1. Išimkite juostą iš pakuotės ir įdėkite į tinkamą juostos laikiklį.
2. Išvyniokite reikiamą ilgį juostos.
3. Juostos galą prilipinkite prie paketo ir prispaudžiant pirštu apsukite aplink paketą. Netempkite juostos skersai paketo, nes jis gali sutrūkinėti.
4. Pakartokite 2 ir 3 punktą, jeigu reikalingos 2 lipnios juostelės paketo sutvirtinimui.
5. Po sterilizacijos garais, cheminio indikatoriaus brūkšniai pakeičia spalvą iš mėlynos į tamsią.
6. Prieš naudojimą juostą perplėškite paketo atidarymo taške, virš sulankstytų kraštų. Nenuplėškite juostos nuo paketų operacinėje, tokiu būdu išvengiant plaušų pasklidimo.

SAUGOJIMAS

- Saugokite kambario temperatūroje (15-30⁰ C) ir esant 10-70% santykinei drėgmei.
- Panaudotus indikatorius laikykite atokiau nuo šviesos šaltinių.
- Nelaikykite arti stipriai šarminių ar rūgštinių produktų, tokių kaip valymo ir dezinfekcijos priemonės. Saugokite atskirai nuo cheminių ir sterilizuojančių medžiagų (pvz. vandenilio peroksidas).
- Panaudojus indikatorius nepakeičia spalvos 6 mėnesius, jeigu laikomasi nurodytų sąlygų.

GALIOJIMO DATA

Galiojimo data yra atspausdinta ant produkto pakuotės. Nenaudokite pasibaigus galiojimo datai.

PARTIJOS (LOT) NUMERIS

Unikalus identifikacijos kodas, LOT numeris yra atspausdintas ant kiekvieno rulono ir pakuotės etiketės.

PAŠALINIAI VEIKSNIAI AR SĄLYGOS

Nėra žinoma pašalinių veiksnių ar sąlygų, kurios galėtų turėti įtakos indikatorius naudojimui ir jo veikimui.

TOKSINIŲ MEDŽIAGŲ IŠSKYRIMAS

Indikatorius neskleidžia jokių toksinių medžiagų, galinčių pakenkti sveikatai ar sterilizuojamam prietaisui.