

AMAX CLASS 5 INTEGRATORS

INDICATOR STRIP LABEL, 19mm X 64mm

AMACSPN-15G

250 strips per Box

AMAX Class 5 Integrators, provides a simple accurate method of ensuring proper conditions for sterilization have been met during a sterilization cycle. They are used as an additional monitoring tool for the release of sterilized loads, and when quarantine is not possible. It will closely mimic the response of a Biological Indicator accurately enough to confidently allow the release of non-implant loads before spore test results are received.




FEATURES

- A new colour change technology; Pink to dark colour transition completely covering the word “NOT” result is a pass.
- A removable adhesive strip to easily place in your record book.

PRODUCT DESCRIPTION

The AMAX Class 5 Integrators contain no lead or other toxic heavy metals. The Indicator Strips are intended for use in steam sterilizers operating at 121°C and up to 135°C. Type 5 Integrating Indicators react to all critical variables (time, temperature and moisture) and reach an end point indicating exposure to sterilization conditions as defined by the stated values outlined below.

The Class 5 Integrator does not replace the routine use of a Biological Indicator.

HOW DO WE COMPARE ?	 Class 5 Integrators	 Comply SteriGage Steam Chemical Integrator	 SteamPlus Type 5 Integrators
Immediate, accurate and easy to read results	✓	✓	✓
Meets performance criteria recommended in ISO 11140-1: 2014 as a Type 5 Integrating Indicator	✓	✓	✓
Package contents (strips per box)	250 / Box	500 / Pkg	100 / Pkg
Price per package *	\$22.49 *	\$99.99 *	\$67.95 *

* Prices may vary

Best practice for sterilization monitoring dictates quarantining instrument loads until the results of the BI test are known.

For *routine loads*, if quarantine is not possible pending BI results, you must use a Type 5 or 6 CI to release instruments.

For sterilizers with a recording device, include a Type 5 or 6 CI in a PCD (commercially manufactured or made in-house) for each load that will be released. Alternatively, include a Type 5 or 6 CI in each instrument package that will be released. Visually verify, document and maintain the results of this CI before releasing instruments.

For sterilizers without a recording device, include a Type 5 or 6 CI in each instrument package that will be released. Visually verify, document and maintain the results of these CI before releasing instruments.

Please note that *implantable devices* must be quarantined until the BI test results are known. ¹

¹Frequently Asked Questions - Infection Prevention and Control, Royal College of Dental Surgeons of Ontario, 2022
<https://www.rcdso.org/en-ca/rcdso-members/running-your-practice/infection-prevention-and-control/frequently-asked-questions>







INSTRUCTIONS FOR USE

Use as a strip or label in each pack, peel pouch or tray intended for steam sterilization. Process packages/items as instructed in the autoclave/sterilizer validation or manual.

Upon exposure to steam, the Indicator will transition from a shade of Pink to Dark. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Pink to Dark and the word "NOT" being completely concealed provides indication of effective steam sterilization conditions. If the signal color is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer malfunction.

The chemical reaction which causes the color transition is a steam specific reaction and is irreversible.

Colors shown are representation of unexposed, ineffective and exposed signal colors but may vary from actual use.

 <p>Color Transition is dependent upon load configuration, cycle parameters and may vary. A color transition from the Initial color to a shade of the signal color which results in the word "NOT" being completely concealed is considered an acceptable transition. If the word "NOT" remains visible, check cycle parameters and equipment function.</p>	Unexposed	Ineffective Cycle	Exposed to Steam 121°C, 16.5 minutes
			

INDICATIONS FOR USE








Type 5 Integrating Indicator stated values

- 121°C, 16.5 minutes (pre-vacuum)
- 135°C, ≥ 1.2 minutes (pre-vacuum)

COMPLIANCE

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators – Part 1: General requirements for Type 5 Integrating Indicators

STORAGE AND SHELF LIFE

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
	Keep away from sterilants. Do not use damaged indicators or indicators which have transitioned to Dark. Do not use after expiration date.		Do not reuse
	<p>Shelf Life 3 years from the date of manufacture. The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 3 years</p>		

DISPOSAL

Discard as general waste.