

FDA 510(k) Clearance Summary

InstruSafe® Instrument Protection Systems are FDA cleared for each sterilization cycle listed below for use with wrap and/or containers as a sterile barrier.

Reference instrusafe.com for the most up to date information.



INSTRUSAFE

STERILIZATION CYCLES + STERILE BARRIERS

Sterilization Cycle	Wrap	InstruSafe Container	Aesculap® Container	Genesis® Container
Steam 4 minute	✓	✓	✓	✓
Ethylene Oxide	✓	✗	✗	✓
STERRAD® 100S Standard	✓	✗	✓	✗
STERRAD® 100NX® Standard	✓	✗	✓	✗
STERRAD® 100NX® Express	✓	✗	✗	✗
STERRAD® 100NX® Flex	✓	✗	✓	✗
STERRAD® NX® Standard	✓	✗	✓	✗
STERIS® AMSCO® V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX + V-PRO® maX 2	✓	✗	✓	✗
Sterizone® VP4	✓	✗	✓	✗

STERILE BARRIERS + FOOT OPTIONS

Sterile barrier and storage needs determine the foot type built into a tray.

STERILE BARRIER	FOOT OPTION
<p>WRAP</p> 	<p>Rounders Corner Guards -R</p> 
<p>CONTAINER</p> 	<p>Tall Feet -TF</p> 

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