

# 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](http://instrusafe.com) for the most up to date information.



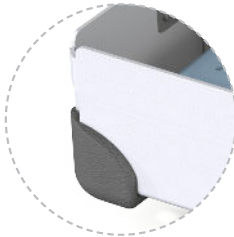
**INTRUSAFE**

## 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><b>WRAP</b></p>       | <p>Rounders Corner Guards -R</p>  |
| <p><b>CONTAINER</b></p>  | <p>Tall Feet -TF</p>              |

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