

Single-Use Tags

(Note: See BROC3138 for Key Surgical® Indicator Dot Tags, see BROC3146 for Key Surgical Reusable Tray Tags)

INTENDED USE:

Key Surgical Tags are identification tools to be used at the discretion of the end user.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

- Tags do not need to be cleaned or disinfected before use.
- Tags can be marked/written on as desired by the end user:
 - Smart Tags and Write-On Tags can be written on with a lab marker that is sterilizable and resistant to alcohol and water
 - If a Scope Tag is to remain on the endoscope post-HLD or when the endoscope is sent out for repair, it is recommended to duplicate the information written on the tag onto a clean tag to avoid re-contamination of the endoscope.
- Secure tag to desired item
 - Some tag designs may require a fastener such as a ring, clip, or tie
- Tags can be sterilized according to the parameters within this IFU
- Tags are single-use and can be sterilized only once
- If processed through manual cleaning and automated cleaning, validation of tag compatibility with facility chemistries and washer/disinfector cycles should be undertaken by the end user.

STERILIZATION:

Tags are provided non-sterile and have been verified for material compatibility according to applicable international process standards and guidance for the methods and parameters within this IFU. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

DISPOSAL:

Tags should be disposed of after use; there are no special disposal instructions.

| Material Compatible with Steam Sterilization | | | |
|---|------------|-----------------|---------------------------|
| Tag Type | Cycle | Temperature | Minimum Time – Full Cycle |
| Locking Tags One-Loop Tags Scope Tags Smart Tags Write-On Tags *Breakaway Tags | Gravity | 121° C (250° F) | 30 minutes |
| Locking Tags One-Loop Tags Scope Tags Smart Tags Write-On Tags *Breakaway Tags | Pre-Vacuum | 132° C (270° F) | 4 minutes |
| Locking Tags Write-On Tags | Pre-Vacuum | 132° C (270° F) | 3 minutes |
| Locking Tags Write-On Tags | Pre-Vacuum | 134° C (273° F) | 3 minutes |

| Material Compatible with STERRAD® | | |
|--|--|------------|
| Tag Type | STERRAD System and Cycle | |
| Locking Tags Scope Tags Smart Tags Write-On Tags *Breakaway Tags | STERRAD® 100S/100S Short | |
| | STERRAD® NX Standard | |
| | STERRAD® 100NX Standard/Express/DUO/Flex | |
| Material Compatible with V-PRO® | | |
| Tag Type | V-PRO System | |
| Locking Tags One-Loop Tags Scope Tags Smart Tags Write-On Tags Breakaway Tags | V-PRO® maX Lumen/Non Lumen/Flexible | |
| | V-PRO® maX 2 Lumen/Non Lumen/Flexible/Fast Non Lumen | |
| | V-PRO® 60 Lumen/Non Lumen/Flexible V-PRO® s2 Lumen/Non Lumen/Flexible | |
| Material Compatible with STERIZONE® | | |
| Locking Tags | STERIZONE VP4 | |
| Material Compatible with 100% EO Sterilization | | |
| One-Loop Tags* | Concentration | 735 mg/L |
| | Temperature | 55° C |
| | Exposure Time | 60 minutes |
| | Humidity | 50-70% |

*The following tags cannot be sterilized in Steam or STERRAD: LR322, LR323, LR324, LR325, LR327, and LR329

* PL3xx One-Loop Tags have not been tested for EO sterilization material compatibility

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MANUFACTURER
FOR US: MANUFACTURED FOR

DO NOT RE-USE

LOT NUMBER REF CATALOG NUMBER

STERIS®