Single-Use Tags

(Note: See BROC-3138 for Key Surgical® Indicator Dot Tags, see BROC-3146 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:

- 1. Tags do not need to be cleaned or disinfected before use.
- 2. 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
 - b. 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.
- 3. Secure tag to desired item
 - a. Some tag designs may require a fastener such as a ring, clip, or tie
- 4. Tags can be sterilized according to the parameters within this IFU
- 5. 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		STERRAD® 100S/100S Short				
Scope Tags						
Smart Tags		STERRAD® NX Standard				
Write-On Tags						
*Breakaway Tags		STERRAD® 100NX				
		Standar	d/Express/DUO/Flex			
Material Compatible with STERIZONE®						
Locking Tags		STERIZONE VP4				
Material Compatible with 100% EO Sterilization						
One-Loop Tags	Concentration Temperature		735 mg/L			
			55° C			
	Exposure Time		60 minutes			
	Humidity		50-70%			

^{*}The following tags cannot be sterilized: LR-322, LR-323, LR-324, LR-325, LR-327, and LR-329



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