

ENDO-ALERT™ - INSTRUCTIONS FOR USE (IFU)

DESCRIPTION:

Designed as a visual timed reminder, ENDO-ALERT™ includes a 7-Day Indicator and 1-Hour Indicator that display elapsed time to support safe endoscope storage and reprocessing.

INTENDED USE:

For use as a visual indicator to identify the expiration status of endoscope reprocessing windows or other time-sensitive stages in the processing workflow.

CONTRADICTIONS:

Do not use on instruments that prohibit external indicators. Do not apply if adhesive backing is compromised or label is damaged.

WARNINGS AND PRCAUTIONS:

- Single-Use Only. Do not reuse.
- Ensure label is securely affixed to a clean, dry surface.
- Use only as intended for visual reminder purposes.
- Do not use if product is expired or damaged.
- Follow facility protocols for interpreting visual expiration cues.

INDICATIONS FOR USE:

Use ENDO-ALERT™ indicators to communicate shelf-life or reprocessing timelines directly on equipment trays, endoscope bins, or carts.

DIRECTIONS FOR USE:

- 1. Fill out the following on the indicator label:
 - Scope Serial Number
 - Name
 - Date
 - Time
- 2. Press the activation button (if present) prior to applying.
- 3. Affix the indicator securely to the item or loop it through a designated holder before use.
- 4. Ensure the label is clearly visible during the designated time window (1 Hour or 7 Days).
- 5. Discard the indicator after expiration. Do not reuse or reapply.

STORAGE CONDITIONS:

Store in a clean, dry environment at room temperature. Avoid direct sunlight, heat, and high humidity.

SHELF LIFE AND DISPOSAL

- Shelf Life: Indefinite if stored under ideal storage conditions (see above).
- Disposal: Discard used indicators with general medical waste per facility policy.

STERILIZATION COMPATIBILITY:

ENDO-ALERT™ does not require sterilization and should not be used inside the sterilizer.

SUPPORTED PRODUCT SKUS:

| SHENA1H SHENA7D |
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NOTE: This IFU applies to all listed product SKUs regardless of packaging configuration.



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