Time Out Visuals

INTENDED USE:

Key Surgical® Time Out Visuals are visual aids intended to prompt surgical staff to perform final verification of surgical procedure details. Actual use of the visuals is at the complete discretion of the user and for visual assistance only.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

- 1. Clean and sterilize Time Out Visuals according to the instructions below.
- 2. Place the sterile Time Out Visual over the surgical instrument during set-up.
- Complete and document all steps of the "TIME OUT" Final Verification Process as outlined in The Joint Commission (TJC) Universal Protocol.
- 4. Remove the Time Out Visual at the start of the procedure.
- 5. Hand the surgical instrument to the surgeon.
- 6. Return the Time Out Visual to the instrument pan.

POINT OF USE CARE:

Clean Time Out Visuals as soon as possible after use. If cleaning must be delayed, immerse in an enzymatic solution or water to prevent drying and encrustation of surgical soil. Avoid prolonged exposure to saline to minimize the chance of corrosion. Remove excessive soil with a disposable wipe.

MANUAL CLEANING:

- 1. Pre-rinse under cold tap water for one (1) minute to remove gross debris
- Soak for a minimum of two (2) minutes in a pH neutral detergent, prepared in according with the manufacturer's instructions for use.
- 3. Rinse under cold tap water for one (1) minute.
- Ultrasonically clean for a minimum of five (5) minutes in a neutral pH detergent, prepared in accordance with the manufacturer's instructions for use.
- 5. Rinse under cold tap water for one (1) minute.

AUTOMATED CLEANING:

It may be necessary to manually clean prior to automated processing to improve the removal of adherent soil. Follow the previous instructions for manual cleaning.

- 1. Load Time Out Visual in a mesh wire tray with concave surface facing downward to facilitate draining.
- 2. Run the automatic wash cycle minimum cycle parameters:
 - 1 minute cold pre-rinse
 - 5 minute enzyme wash at 43° C minimum temperature
 - 1 minute cold rinse
 - 7 minute dry at 90° C minimum temperature

CLEANING INSPECTION:

Visually inspect before sterilization or storage to ensure the complete removal of soil from surfaces. If soil is still present, re-clean the Time Out Visual.

TIME OUT VISUAL CARE:

- 1. Stacking the Time Out Visuals may lead to scratching and inadequate sterilization effectiveness.
- 2. To avoid staining, use a pH neutral cleaning solution.
- 3. Inspect regularly for pitting and rusting.
- 4. Fading of lettering color and scratches may occur after multiple uses.

STERILIZATION:

The Time Out Visuals have been tested for sterilization compatibility according to applicable international process standards and guidance for the following methods and parameters:

Cycle Type (Steam)	Temperature	Minimum Time – Full Cycle
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes

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:

Time Out Visuals have a life span and will require replacing if there are any signs of deterioration or loss of functionality. Dispose of product following facility policy for disposal.



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