KeyDot®

EN - INTENDED USE:
Key Surgical KeyDot is intended for tracking individual surgical instruments and is used in conjunction with appropriate instrument tracking software designed for instrument identification, inventory status, and management. KeyDot is intended for one-time application/adhesion to the instrument and should not be reapplied if removed.

MATERIAL:
KeyDot is made from a 3M specialty film label material designed to withstand harsh environments and temperature conditions.
- Top layer: 0.4 mil (10 microns) matte black acrylate
- Base layer: 2.0 mil (50 microns) matte white acrylate
- Adhesive: 1.2 mil (30 microns) #350 high-holding acrylic

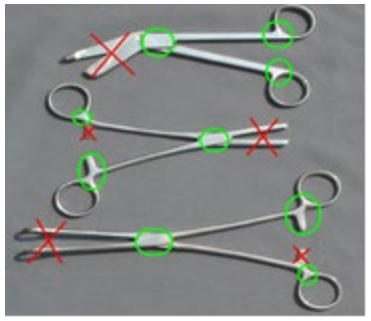
KeyDot can be adhered to:
- Stainless steel
- Engineered thermoset polymer (medical-grade plastic)

CLEANING & DISINFECTION:
KeyDot is compatible with the following high-level disinfectants:

OPA/28
Glutaraldehyde 3%

Using a pH-neutral detergent, prepare instruments with dosing and concentration according to the detergent manufacturer's instructions for use.

INSTRUCTIONS FOR USE:
1. Select a KeyDot that is sized appropriately to the location of the instrument to which it will be applied. To ensure proper adhesion, the KeyDot should not be larger than the application location.
2. Ensure the instrument has been thoroughly washed before beginning the application process. If necessary, use adhesive remover to remove any adhesive residue. Rewash the instrument thoroughly before continuing with the KeyDot application.
3. Choose a suitable location to which you will apply the KeyDot. Do not place the KeyDot on or near the working end of the instrument. A flat surface is best.



4. Clean the area with isopropyl alcohol to remove moisture and allow to dry. Use a surgical towel or lint-free wipe and dip in a bowl of alcohol. Disposable alcohol towelettes may be used but be sure to use a new towelette if the alcohol evaporates.

5. Once the alcohol has dried, use tweezers or forceps to remove the KeyDot from the KeyDot sheet and immediately apply it to the selected location. Do not touch the exposed adhesive of the KeyDot or the cleaned area of the instrument. Unclean surfaces, from oils and debris on fingers, can interfere with successful bonding.

6. Using the round end of the purple applicator tool, apply firm pressure to the center of the KeyDot and work towards the outside in a circular motion. This pressure activates the pressure-sensitive adhesive and smooths the edge of the KeyDot. Alternatively, you can apply firm pressure to the KeyDot using an index finger, while wearing gloves, to activate the adhesive.

7. Sterilize the instrument to cure the adhesive and ensure a complete bond.
   Note: If instrument is not sterilized after KeyDot application, the adhesive requires 72 hours to fully cure.
8. Do not soak or wash the instrument until it has been fully cured.

STERILIZATION:
Provided non-sterile and have been validated for steam sterilization at the following cycle parameters:

Steam Sterilization		
Cycle Type	*Temperature*	*Minimum Time – Full Cycle*
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes
Pre-Vacuum	134° C (273° F)	18 minutes
Pre-Vacuum	134° C (273° F)	3 minutes

Validated for sterilization efficacy in a 100% Ethylene Oxide (EtO) sterilization cycle:

100% Ethylene Oxide (EtO)	
Concentration	725 mg/L
Temperature	55° C
Exposure Time	60 min
Humidity	50-80%

Validated for sterilization efficacy in the following STERRAD® Systems and cycles:

STERRAD System and Cycle
STERRAD 100S/100S Short STERRAD NX Standard STERRAD 100NX Standard/Express/DUO/Flex

Validated for sterilization efficacy in the following STERIZONE® System:

STERIZONE System
STERIZONE VP4

Validated for sterilization efficacy for the following V-PRO® Systems and cycles:

V-PRO System and cycle
V-PRO maX Lumen Cycle
V-PRO maX 2 Lumen Cycle

KeyDot can withstand repeated sterilization cycles. Sterilization efficacy test results indicate that both the KeyDot and the underlying instrument surface were fully sterile under the conditions of the study.

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.

BIOCOMPATIBILITY AND CYTOTOXICITY INFORMATION:
Key Surgical has completed biocompatibility and cytotoxicity testing on KeyDot. All testing was performed under Good Laboratory Practices (FDA, 21 CFR, Part 58) by an approved testing facility.

Biocompatibility testing was completed in accordance with the ISO test method requirements for implantation in subcutaneous tissue ANSI/AAMI/ISO 10993-6, Biological Evaluation of Medical Devices –Part 6: Tests for local effects after implantation.

- Based on the results of the clinical, gross, and microscopic observations, KeyDot is considered a “non-irritant”.

Cytotoxicity testing was completed in accordance with the test method requirements specified in ANSI/AAMI/ISO 10993-5: Biological Evaluation of Medical Devices – Part 5: Tests for cytotoxicity, in-vitro methods.

- Based on the results of the cytotoxicity test scores, KeyDot is considered non-toxic.

BARCODE:
Data Matrix ECC-200 standard symbology barcodes are laser-engraved into the top layer of the label material, exposing the white base layer.

- White barcode on black background provides excellent contrast for barcode readability.
- Highly redundant Data Matrix provides readability with up to 60% destruction of barcode.
- All KeyDot barcodes are verified to be readable.
- All KeyDots are created with a unique barcode number. We guarantee that no duplicate numbers will be created unless specified for custom request items.

STORAGE:
Store away from direct sunlight or heat. Do not apply when the temperature is below 39° F.

DISPOSAL:
Requires replacing if there are any signs of deterioration or loss of functionality. Dispose according to facility protocol.