KEYSURGICAL®

KeyDot®

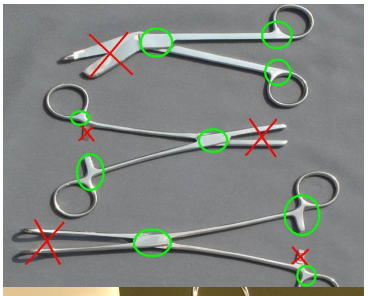
Intended Use:

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 to adhere to the instrument and should not be reapplied if removed.

Follow the instructions below to ensure a proper bond between the KeyDot and the instrument.

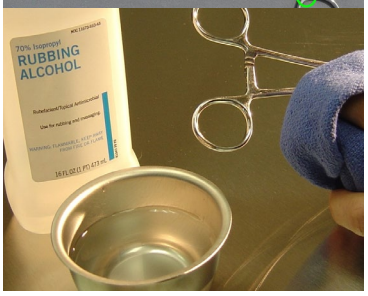
1. **Select an appropriate size KeyDot for the application site on the instrument.**
    - Select a KeyDot that is sized appropriately to the location of the device that it will be applied. The KeyDot should not be larger than the application site to ensure proper adhesion.

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 area to which you will apply the KeyDot.**
    - Place the KeyDot away from the working end of the instrument. A flat surface is best.

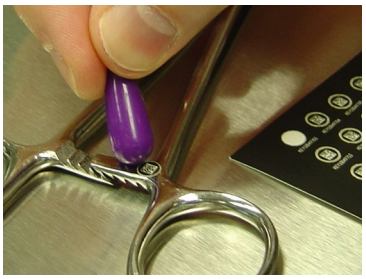
4. **Clean the area with isopropyl alcohol and allow to dry.**
    - Alcohol is used to remove moisture.
    - Use a surgical towel or O.R. rag and dip in a bowl of alcohol. Disposable towelettes may be used but replaced after use on a few instruments or when the alcohol evaporates.



5. **Once the alcohol has dried, use tweezers or forceps to remove the KeyDot from the liner and immediately apply it to the selected area.**
    - 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 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 smoothes the edge of the KeyDot. Alternatively, apply firm pressure to the KeyDot using an index finger, while wearing gloves, to activate the adhesive.

7. **Sterilize the instrument in order to cure the adhesive and ensure a complete bond.**
    - Without sterilizing, the adhesive will fully cure in 72 hours.



8. **Do not put the instrument through any soaks or washes until it has been fully cured.**

    - KeyDot is not intended as a permanent mark and may break, chip, or flake over time. Replace as necessary.

KeyDot®

Storage Information

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

Disinfection/Cleaning Information

- KeyDot is compatible with the following High-Level Disinfectants:

OPA/28
Glutaraldehyde 3%

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

Sterilization Information

- KeyDot is provided non-sterile and has been validated for steam sterilization at the following cycle parameters:

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

- KeyDot has been validated for sterilization efficacy in a 100% Ethylene Oxide (EtO) sterilization cycle:

Concentration	725 mg/L
Temperature	55° C
Exposure Time	60 minutes
Humidity	50-80%

- KeyDot has been validated for sterilization efficacy in the following STERRAD® Systems and cycles:

STERRAD® System and Cycle within the United States	*STERRAD® System and Cycle outside United States*
STERRAD® 50	*STERRAD® 50*
STERRAD® 200	*STERRAD® 200 Short cycle*
STERRAD® 100S	*STERRAD® 100S Short cycle*
STERRAD® NX Advanced cycle	*STERRAD® NX Advanced cycle*
STERRAD® NX Standard cycle	*STERRAD® NX Standard cycle*
STERRAD® 100NX Standard cycle	*STERRAD® 100NX Standard cycle*

- KeyDot has been validated for sterilization efficacy in the following STERIZONE® System:

STERIZONE® System	STERIZONE® VP4

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

KeyDot®

Biocompatibility and Cytotoxicity Information

Key Surgical has completed biocompatibility and cytotoxicity testing on the 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, the 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, the KeyDot is considered “non-toxic.”

Material and Adhesive Information

KeyDots are made from a 3M specialty film label material that is designed to withstand harsh environmental 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

Material Compatibility

KeyDot can be adhered to:

- Stainless Steel
- Engineered thermoset polymer (medical grade plastic)

Barcode

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

KeyDot can withstand repeated sterilization cycles.

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.