STERILE BITS™ INSTRUMENT PROTECTOR BACKER CARDS

PRODUCT DESCRIPTION:

The Sterile Bits™ Instrument Protector Backer Card is a backer board component that provides enhanced structural integrity of a sterile package solution for surgical instruments and/or implants. The Instrument Protector Backer Card provides a mounting surface intended to hold and maintain a product intended for packaging and sterilization. Products mounted onto the Instrument Protector Backer Card are intended to be placed into a sterile barrier (i.e. pouch or blister). Instrument Protector Backer Cards enhance sterile barrier (i.e. pouch) integrity by limiting product movement within the package. Limiting product movement within a package minimizes the possibility for the packaged product to break and/or violate a sterile barrier (i.e. pouch) material, seals, and/or borders.

Instrument Protector Backer Cards are made from Solid Bleached Sulfate (SBS). SBS is a bleached virgin fiber grade of paperboard which is the highest quality paperboard substrate available and is used in high-end packaging applications where a moisture barrier is important.

INDICATIONS FOR USE:

The Sterile Bits™ Instrument Protector Backer Card is intended to be used in terminally sterilized packaging for various surgical instruments and/or implants. The SBS material is Steam Sterilization or EO (ethylene oxide) friendly.

CONTRAINDICATIONS:

None.

WARNINGS and PRECAUTIONS:

- Instrument Protector Backer Cards are generic components available for use in a total / final package solution. End use and effectiveness liability resides with the end-user.
- Sterile Bits makes no packaging or sterilization validation claims. End users must assess packaging integrity and sterilization integrity based on end-use application.
- Instrument Protector Backer Cards are intended for single use. Do not reuse.
- Instrument Protector Backer Cards shall be used in conjunction with a sterile barrier (i.e. pouch or blister).

DIRECTIONS FOR USE:

1. Convert flat pattern Instrument Protector Backer Card into a 3D structural state by folding bottom flap over 180°. Insert two (2) locking tabs into the two (2) tab receiving slots at the bottom of the Instrument Protector Backer Card. Images 1A and 1B show a before & after conversion of the Instrument Protector Backer Card.
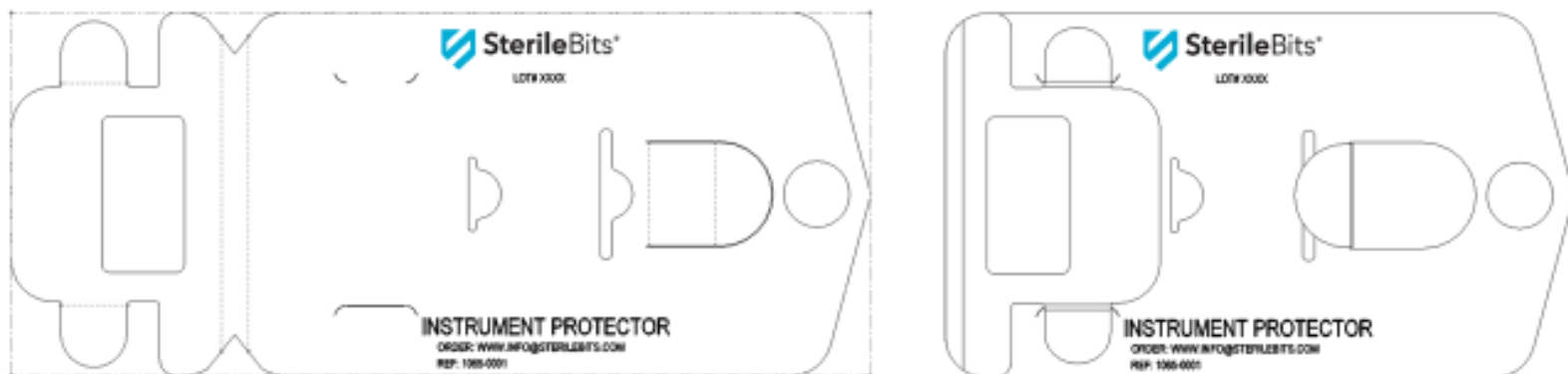

Figure 1A (left) / 1B (right): Convert Flat Pattern Instrument Protector Backer Card into a 3D Structural State

2. Mount instrument or implant to Instrument Protector Backer Card (image 2).
 - 1st Feed product through large "top hat" slot through to the backside of the card.
 - 2nd Feed product through small "top hat" slot through to the front of the card.
 - 3rd Position working end of product into bottom fold over pocket.
 - 4th Open product (if applicable) such that pivot arms extend to outer most boundary of large "top hat" slot.
 - 5th Fold tongue down over product pivot arms (if applicable) and through "top hat" slot. Pull tight to secure product

3. Place Instrument Protector Backer Card with mounted product inside a sterile barrier and complete final packaging.
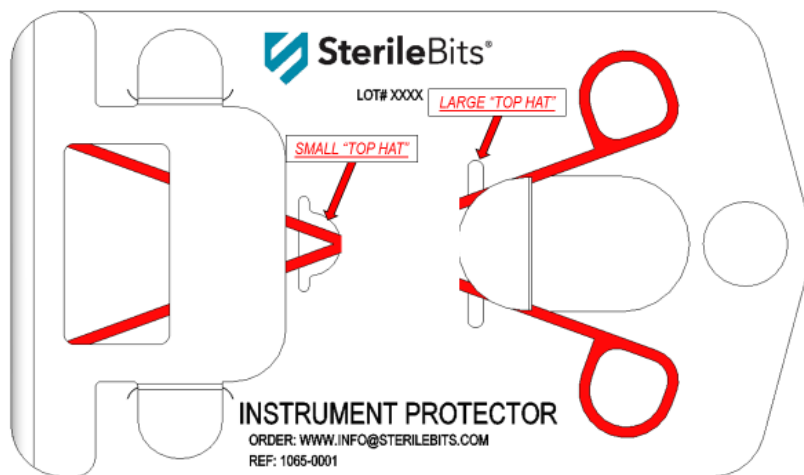

Figure 2: Mount Instrument or Implant to Instrument Protector.

WARRANTY DISCLAIMER AND LIMITATIONS:

Inspect product upon receipt to ensure no package breach or damage has occurred prior to use. Sterile Bits will not accept open returns. Sterile Bits is not liable for end use package integrity. The end user assumes all responsibilities and liabilities for end use package function.

For product information or questions concerning use, contact Sterile Bits directly.

STORAGE AND SHELF LIFE:

Instrument Protector Backer Cards should be kept in dry conditions (<50% relative humidity) at indoor room temperature (15-30°C / 59-86°F). Instrument Protector Backer Cards should be stored in original packaging or in an equivalent clean barrier to maintain cleanliness.

MANUFACTURER INFORMATION:

Sterile Bits: 1-800-459-1587
www.sterilebits.com
info@sterilebits.com

Do not re-sterilize	Non-Sterile (Instrument Protectors are provided non-sterile)	Do not use if package is damaged	Keep Dry	Do not re-use	Consult Instructions for Use