

STERILEBITS™ ROBOTIC ARM STERILIZATION CARD G2



PRODUCT DESCRIPTION:

The SterileBits™ Robotic Arm Sterilization Card is a backer board component that provides enhanced structural integrity of a sterile package solution for surgical instruments and/or implants. The Robotic Arm Sterilization Card provides a mounting surface intended to hold and maintain a product intended for packaging and sterilization. Products mounted onto the Robotic Arm Sterilization Card are intended to be placed into a sterile barrier (i.e. pouch). Robotic Arm Sterilization 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.

INDICATIONS FOR USE:

The SterileBits™ Robotic Arm Sterilization 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:

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

DIRECTIONS FOR USE:

1. Convert flat pattern Robotic Arm Sterilization Card into a 3D structural state by folding left most flap and right most flap 180° to achieve 3D state. Note that provided score lines indicate where to make folds. Figure 1A and 1B show a before & after conversion of the Robotic Arm Sterilization Card from a flat state to a 3D state.

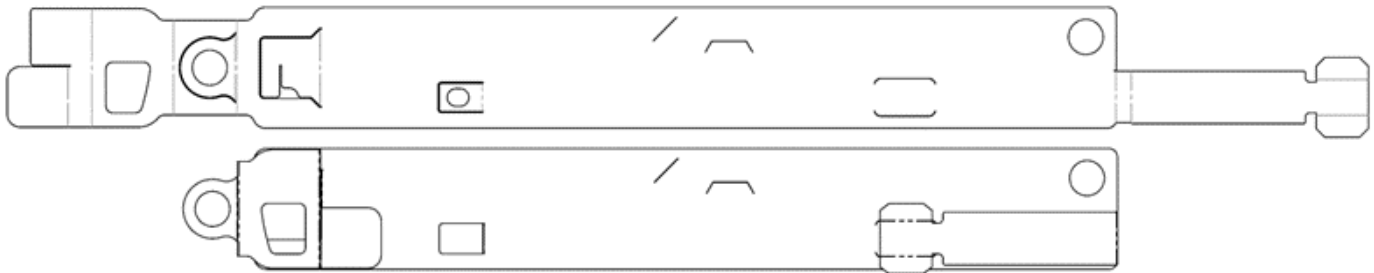


Figure 1A (top) / 1B (bottom): Convert Flat Pattern Robotic Arm Sterilization Card into a 3D Structural State

2. Prepare Folded Backer Card for Robotic Instrument Assembly. Figure 2 identifies the features described below.
 - 1st Insert two (2) Right Side Locking Tabs into the two (2) tab receiving slots at the right side the Robotic Instrument Protector Backer Card. This will form a small pocket.
 - 2nd Fold Eyelet in to the “Up” position.

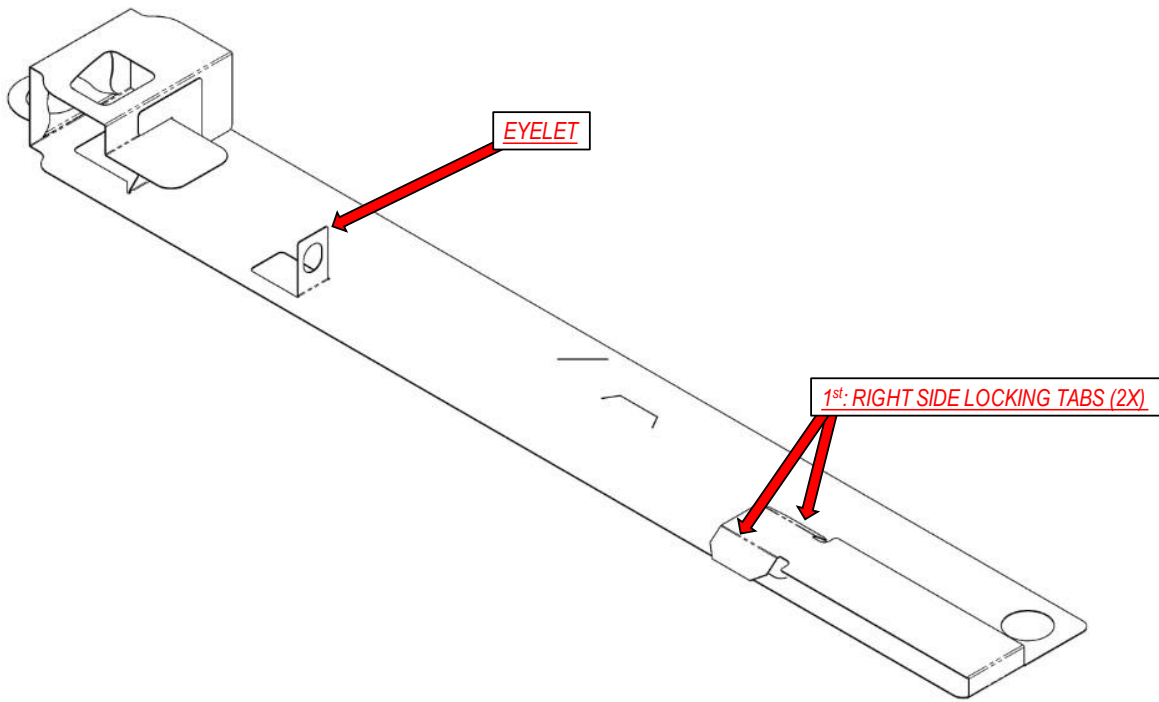


Figure 2: Prepare Folded Backer Card for Robotic Assembly

3. Place Robotic Instrument onto Robotic Arm Sterilization Card (figure 3).
 - 1st Feed shaft through Eyelet.
 - 2nd Feed shaft into the formed pocket at the right side of the card.
 - 3rd Position body of Robotic Instrument flat on card so that the left side of the Robotic Arm Sterilization Card may be finish assembled.

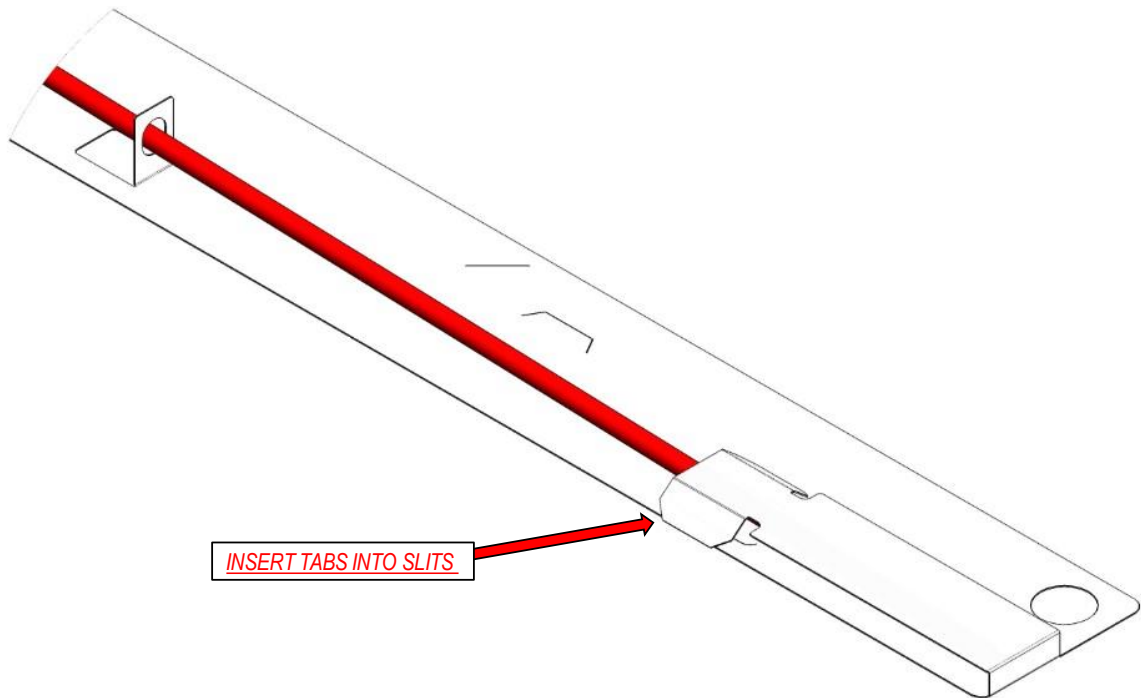


Figure 3: Feed Shaft through eyelet and into pocket formed at right side of card.

4. Tuck Robotic Instrument Head into Left Side Folds of Robotic Arm Sterilization Card (figure 4).
 - 1st Fold and Tuck Left Hand Flap to block in Robotic Instrument Head.
 - 2nd Fold and Tuck Shaft Flap to Robotic Instrument Shaft.
 - 3rd Fold and Tuck Interlock Flap

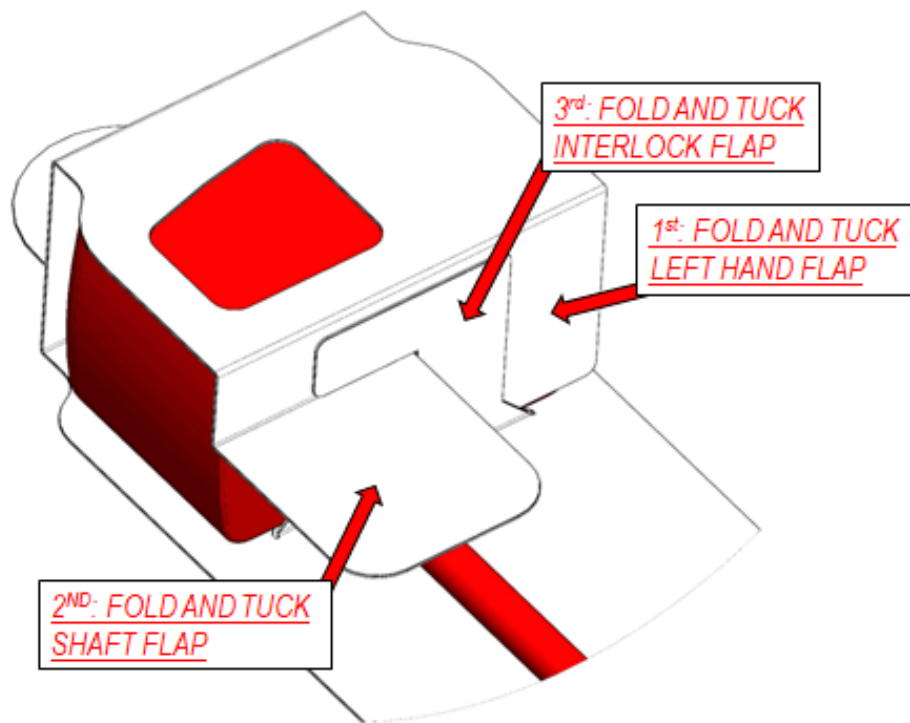


Figure 4: Tuck Robotic Instrument Head into Left Side Folds.

5. Fold up Folding Flap Finger Ring (figure 5).

- 1st Fold up Folding Flap Finger Ring (figure 5). Figure 5 shows the Folding Flap Finger Ring in the product removal position.
- 2nd Note the secondary Flat Finger Ring at the opposite end of the Robotic Arm Sterilization Card.

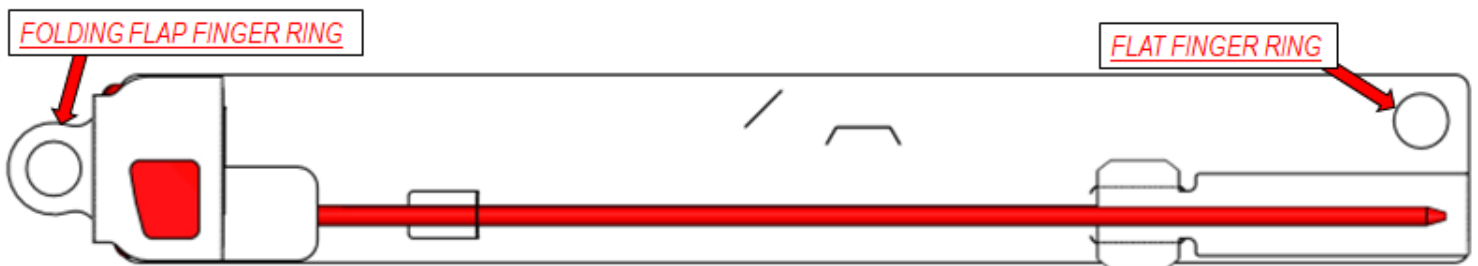


Figure 5: Finished Assembly

WARRANTY DISCLAIMER AND LIMITATIONS:

Inspect product upon receipt to ensure no package breach or damage has occurred prior to use. SterileBits will not accept open returns. SterileBits 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 SterileBits directly.

STORAGE AND SHELF LIFE:

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

MANUFACTURER INFORMATION:



SterileBits: 1-800-459-1587

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