

## **In Vitro Linear Coverage of SURGISEAL<sup>®</sup> in Stylus Applicator**

Test Article: SURGISEAL<sup>®</sup> in Stylus Applicator (Lot 11223i, 11224i, and 11244i)

Performing Laboratory: Adhezion Biomedical, LLC  
506 Pine Mountain Road  
Hudson, NC 28638



### INTRODUCTION:

This test method is intended to determine the linear coverage of SURGISEAL® in Stylus applicator on pig skin.

### MATERIALS:

1. SURGISEAL® (Lot 11223i, 11224i, and 11244i)
2. Pig Skin supporting fat layer
3. Ruler
4. Sterile Gauze
5. Isopropyl Alcohol

### METHOD:

SURGISEAL® in Stylus applicator as applied in a light layer through its foam applicator tip onto pig skin until all the adhesive is dispensed from the applicator. The linear coverage of SURGISEAL® was measured with a ruler.

### PROCEDURE:

- a. Prepare pig skin by wiping the surfaces of the skin with sterile gauze saturated with isopropanol and make sure to remove all oily substances from the pig skin.
- b. Then wipe the surface with dry pieces of gauze.
- c. Brush the SURGISEAL® Stylus applicator from left to right dispensing a light layer of SURGISEAL® onto pig skin until the entire adhesive in one applicator is distributed
- d. Measure the length of the adhesive strokes appeared onto pig skin.
- e. Add the length of all strokes to obtain the linear surface coverage
- f. Repeat the process ten times.



Figure 1. One selected sample of Stylus SURGISEAL® adhesive strokes applied onto pig skins

## RESULTS

SURGISEAL® in Stylus applicator (lot 11223i, 11224i, and 11244i) was sterilized by Gamma sterilization at 15.3-16.6 kGy. The linear coverage of SURGISEAL® in Stylus applicator was measured by measuring the adhesive strokes applied onto the pig, as shown in Figure 1.

The test was repeated ten times and the result was summarized in Table 1. The average linear coverage of SURGISEAL® in Stylus applicator is 263.25 cm (103.64 inch). As reported previously, the average linear coverage of SURGISEAL® in Teardrop applicator is 185 cm (74 inch). The average linear coverage of Dermabond was also reported earlier, which is 182.3 cm (72.9 inch).

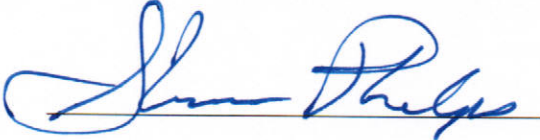
Table 1: Linear coverage of SURGISEAL® in Stylus applicator

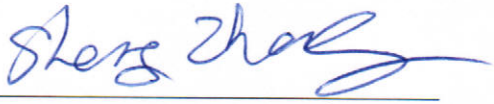
Sample	SURGISEAL® in Stylus applicator										
	1	2	3	4	5	6	7	8	9	10	average
Linear coverage (cm)	284.5	250.4	259.5	257.4	266.1	265.8	258.9	272.7	262.6	254.6	<b>263.25</b>
Linear coverage (inch)	112.0	98.6	102.2	101.3	104.8	104.6	101.9	107.4	103.4	100.2	<b>103.64</b>


**CONCLUSION:** The linear coverage per applicator for SURGISEAL® in Stylus applicator on pig skin is 263.25 cm (103.64 inch), which is longer than those of Dermabond adhesive and SURGISEAL® in Teardrop applicator.

**Analysts' Signature:**

Investigators and analysts for the linear coverage of SURGISEAL<sup>®</sup> in Stylus applicator

Analyst:       08-17-11  
Shannon Phelps      Date

Study Director:       08-17-11  
Sheng Zhang      Date

Management:       08-17-11  
Rafael Ruiz      Date