

Appendix 1

Case Report Form (CRF)

Site _____ Department _____ Investigator _____

1. Subject information

- Initial:
- Date of birth:
- Gender:
- Diagnosis:
- Surgery (Emergency Regular):
- Surgery date (Date of SurgiGuard® Use):
- Comorbidity:

<input type="checkbox"/> Hypertension	<input type="checkbox"/> Diabetes	<input type="checkbox"/> Liver disease
<input type="checkbox"/> Renal disease	<input type="checkbox"/> other	
- Concomitant drug

<input type="checkbox"/> Antihypertensive	<input type="checkbox"/> Hypoglycemic agent	<input type="checkbox"/> Liver disorder
<input type="checkbox"/> Anticoagulant	<input type="checkbox"/> Hormone	<input type="checkbox"/> Immunosuppressant
<input type="checkbox"/> other		

2. Usage of SurgiGuard®

2.1 SurgiGuard® Product name

- | | |
|--|---|
| <input type="checkbox"/> SurgiGuard® Original | <input type="checkbox"/> 5 cm x 7.5 cm (2inch x 3inch)
<input type="checkbox"/> 5 cm x 35 cm (2inch x 14inch)
<input type="checkbox"/> 10 cm x 20 cm (4inch x 8inch)
<input type="checkbox"/> 1.25 cm x 5 cm (0.5inch x 2inch) |
| <input type="checkbox"/> SurgiGuard® Fabric | <input type="checkbox"/> 5 cm x 7.5 cm (2inch x 3inch)
<input type="checkbox"/> 7.5 cm x 10 cm (3inch x 4inch)
<input type="checkbox"/> 15.2 cm x 22.9 cm (6inch x 9inch)
<input type="checkbox"/> 2.5 cm x 2.5 cm (1inch x 1inch)
<input type="checkbox"/> 2.5 cm x 7.5 cm (1inch x 3inch) |
| <input type="checkbox"/> SurgiGuard® Fibrillar | <input type="checkbox"/> 2.5 cm x 5.1 cm (1inch x 2inch)
<input type="checkbox"/> 5.1 cm x 10.2 cm (2inch x 4inch)
<input type="checkbox"/> 10.2 cm x 10.2 cm (4inch x 4inch) |
| <input type="checkbox"/> SurgiGuard® Non-woven | <input type="checkbox"/> 2.5 cm x 5.1 cm (1inch x 2inch)
<input type="checkbox"/> 5.1 cm x 10.2 cm (2inch x 4inch)
<input type="checkbox"/> 10.2 cm x 10.2 cm (4inch x 4inch) |

2.2 Number of SurgiGuard® used in surgery

- 1
- 2
- 3

- 4
- More than 5

2.3 Whether you use SurgiGuard® alone or in combination with other products?(When using combination, please select a duplicate)

- SURGIGUARD (ORC)
- SURGICEL (ORC)
- EVICEL (Fibrin)
- TACHOSIL (Fibrin)
- TISSEEL (Fibrin)
- GREENPLAST (Fibrin)
- BERIPLAST (Fibrin)
- FLOSEAL (Fibrin)
- COSEAL (Synthetic Sealant)
- DURASEAL (Synthetic Sealant)
- BIOGLUE (Albumin Sealant)
- AVITENE (Collagen)
- COLLAPAD (Collagen)
- BLEESTOP (Collagen)
- other ()

2.4 Removal of SurgiGard® after hemostasis

- Removed
- Not removed
- other ()

3. SurgiGard® Hemostatic effect

3.1 Hemostasis effect of SurgiGuard® as hemostasis supplement(6 point scale)

: _____ points (Please, display the first decimal place)

Extremely satisfied (6)	Very satisfied (5)	Somewhat satisfied (4)	Somewhat dissatisfied (3)	Very dissatisfied (2)	Extremely dissatisfied (1)

3.2 User Satisfaction with SurgiGuard® Surgical Handling as hemostasis supplement

Extremely satisfied (6)	Very satisfied (5)	Somewhat satisfied (4)	Somewhat dissatisfied (3)	Very dissatisfied (2)	Extremely dissatisfied (1)

3.3 If there was no hemostatic effects (1-2 point), why?

- Comorbidity (Liver disease, Renal disease, Sepsis, etc)

- Extensive bleeding
- Vascular injury
- Concomitant drug (Aspirin, Wafarin, Platelet aggregation inhibitor, etc)
- Lack of SurgiGuard® usage (Use less than the right amount or the right size)
- other ()

4. Operative characteristics

- Intraoperative blood loss (ml): _____ml
- Intraoperative blood transfusion: Yes No
- Pre/Post-operative hemoglobin level
 - ① Pre-operative Hemoglobin: _____
 - ② Post-operative day-1 Hemoglobin: _____
- Postoperative drain tube insertion: Yes No
 - ① If yes, drainage volume within 1 day after operation: _____ml
- Re-bleeding after using SurgiGuard®: Yes No
 - ① If there **was no re-bleeding**, the time until the complete hemostasis was confirmed after the surge guard was applied: () min
 - ② If there **was re-bleeding**, the time from to re-bleeding after SurgiGuard® application: () min
 - ③ Treatment for re-bleeding: **(When using the combination, please select a duplicate)**
 - SURGIGUARD (ORC)
 - SURGICEL (ORC)
 - EVICEL (Fibrin)
 - TACHOSIL (Fibrin)
 - TISSEEL (Fibrin)
 - GREENPLAST (Fibrin)
 - BERIPLAST (Fibrin)
 - FLOSEAL (Fibrin)
 - COSEAL (Synthetic Sealant)
 - DURASEAL (Synthetic Sealant)
 - BIOGLUE (Albumin Sealant)
 - AVITENE (Collagen)
 - COLLAPAD (Collagen)
 - BLEESTOP (Collagen)
 - other ()
 - ④ Reoperation due to bleeding after the operation: Yes No

5. Adverse events after using SurgiGuard® (Side effects)

- 5.1 Adverse events occurred within 24 hours after surgery
- Yes No

- 5.2 If there was an adverse events
- Requiring transfusion blood products
 - Bleeding/leakage from treated site

- Hemorrhage
- Allergic Reaction
- Abscess
- Granuloma
- Obstruction
- Stroke
- Ischemia
- Sepsis
- Infection
- Deep Vein Thrombosis
- Cellulitis
- Ischemia
- Pericardial Effusion
- Respiratory dysfunction
- other ()

5.3 Relationship between Adverse Events and SurgiGard®

- Related
- Not related
- Not evaluable