

Tricol Biomedical Evaluation Form Vascular Closure

Directions: Please fill out with as much detail as possible.

Section 1

1. **Date:**
2. **Facility Name:**
3. **Evaluator First and Last Name:**
4. **Title:**
5. **Evaluator Phone Number:**
6. **Evaluator Email Address:**
7. **Department: Please check department where used:**
 - Cath Lab
 - IR
 - EP
 - ICU
 - Other

Section 2

1. **What protocol and product(s) does your facility use today to control bleeding after sheath removal?**

2. **What protocol and product(s) does your facility use today to control bleeding from indwelling catheters or lines?**

3. **What do you like about these products?**

4. **What would you change about these products if you could?**

Section 3

1. Please specify the Tricol device used for evaluation.
 - 1102 OneStop Vascular 1.5 inch
 - 1103 OneStop Vascular 2.0 inch
 - 1104 OneStop Vascular 1.5in Pre-Slit 4mm hole
2. Did you reference the product IFU for specific instructions? Yes No
3. Did you view the application and removal video? Yes No
4. Were you given training on Tricol's mechanism of action? Yes No

Section 4:

1. Patient Tracking Number:
2. Name of procedure the patient underwent:
3. Access site: Femoral Brachial Radial Other
4. What French size sheath was used in this procedure?
5. Were ACT levels monitored before application of Tricol device?
 - a. If yes, were they below 200? Yes No
6. Did you ensure that the area around the access site was not cleaned before Tricol patch application? Yes No
7. When sheath was removed, how much blood did you allow to pool before patch application? Small coin size No blood
8. Was pressure on the dressing held without moving, peeking or dislodging? Yes No
9. Was hemostasis achieved according to Tricol IFU and facility protocol? Yes No
10. How long was pressure held before hemostasis was achieved?
11. Did you secure the patch with an appropriate dressing after achieving hemostasis? Yes No

Tricol devices are made of chitosan and are safe to use on patients with shellfish allergies. They are able to rapidly control bleeding, provide an antibacterial barrier at the wound site, and are effective for patients on anticoagulation therapy. Tricol devices can be left in place for up to 48 hours and then easily removed after saturating with water or saline.

Fill out the below if there were additional evaluations:

Second Evaluation

1. Patient Tracking Number:
2. Name of procedure the patient underwent:
3. Access site: Femoral Brachial Radial Other
4. What French size sheath was used in this procedure?
5. Were ACT levels monitored before application of Tricol device?
 - a. If yes, were they below 200? Yes No
6. Did you ensure that the area around the access site was not cleaned before Tricol patch application? Yes No
7. When sheath was removed, how much blood did you allow to pool before patch application? Small coin size No blood
8. Was pressure on the dressing held without moving, peeking or dislodging? Yes No
9. Was hemostasis achieved according to Tricol IFU and facility protocol? Yes No
10. How long was pressure held before hemostasis was achieved?
11. Did you secure the patch with an appropriate dressing after achieving hemostasis? Yes No

Third Evaluation

1. Patient Tracking Number:
2. Name of procedure the patient underwent:
3. Access site: Femoral Brachial Radial Other
4. What French size sheath was used in this procedure?
5. Were ACT levels monitored before application of Tricol device?
 - a. If yes, were they below 200? Yes No
6. Did you ensure that the area around the access site was not cleaned before Tricol patch application? Yes No
7. When sheath was removed, how much blood did you allow to pool before patch application? Small coin size No blood
8. Was pressure on the dressing held without moving, peeking or dislodging? Yes No
9. Was hemostasis achieved according to Tricol IFU and facility protocol? Yes No
10. How long was pressure held before hemostasis was achieved?
11. Did you secure the patch with an appropriate dressing after achieving hemostasis? Yes No

Fourth Evaluation

1. Patient Tracking Number:
2. Name of procedure the patient underwent:
3. Access site: Femoral Brachial Radial Other
4. What French size sheath was used in this procedure?
5. Were ACT levels monitored before application of Tricol device?
 - a. If yes, were they below 200? Yes No
6. Did you ensure that the area around the access site was not cleaned before Tricol patch application? Yes No
7. When sheath was removed, how much blood did you allow to pool before patch application? Small coin size No blood
8. Was pressure on the dressing held without moving, peeking or dislodging? Yes No
9. Was hemostasis achieved according to Tricol IFU and facility protocol? Yes No
10. How long was pressure held before hemostasis was achieved?
11. Did you secure the patch with an appropriate dressing after achieving hemostasis? Yes No

Fifth Evaluation

1. Patient Tracking Number:
2. Name of procedure the patient underwent:
3. Access site: Femoral Brachial Radial Other
4. What French size sheath was used in this procedure?
5. Were ACT levels monitored before application of Tricol device?
 - a. If yes, were they below 200? Yes No
6. Did you ensure that the area around the access site was not cleaned before Tricol patch application? Yes No
7. When sheath was removed, how much blood did you allow to pool before patch application? Small coin size No blood
8. Was pressure on the dressing held without moving, peeking or dislodging? Yes No
9. Was hemostasis achieved according to Tricol IFU and facility protocol? Yes No
10. How long was pressure held before hemostasis was achieved?
11. Did you secure the patch with an appropriate dressing after achieving hemostasis? Yes No