INITIER LA PROCÉDURE EN CAS DE RUPTURE DE MEMBRANE D'UN DIALYSEUR EN HÉMODIALYSE			
Direction(s) responsable(s)	Direction des soins infirmiers et de l'enseignement universitaire	Approuvé	2016-05
	Direction des services professionnels et de l'enseignement médical	Révisé	2018-04-10
Installations / Secteurs visés	Centre de suppléance rénale Louise-Auger Centre de dialyse Guy-Beauchamp de l'Hôpital du Suroît Centre intrahospitalier d'hémodialyse de l'Hôpital Anna-Laberge		
Outils cliniques associés			

1. Professionnels visés

Les infirmières[1]

[1] Les infirmières habilitées à appliquer l'ordonnance collective doivent avoir reçu la formation nécessaire selon le programme de formation spécifique en hémodialyse.

2. Activités réservées

- Effectuer et ajuster les traitements médicaux, selon une ordonnance.
- Initier des mesures diagnostiques et thérapeutiques selon une ordonnance.

3. Situations cliniques visées/clientèles visées

Usagers hémodialysés

4. Intentions thérapeutiques

Prévenir et minimiser les complications chez les usagers hémodialysés lors d'une rupture de la membrane d'un dialyseur.

5. Indications

Alarme « fuite de sang » ou « détection de sang » sur l'appareil d'hémodialyse indiquant une rupture de la membrane d'un dialyseur.

6. Contre-indications

Aucune

7. Conditions d'initiation

Identiques à la section « Indications »

8. Limites/références au médecin

Lors du prochain traitement d'hémodialyse, aviser le néphrologue :

- De la rupture de la membrane du dialyseur et du résultat Hb-Ht effectué lors du traitement d'hémodialyse suivant l'incident.

9. Directives

1. Visualiser l'alarme « fuite de sang » ou « détection de sang ».
2. Arrêter la pompe à sang. **S'il reste moins de 30 minutes au traitement d'hémodialyse, cesser celui-ci.**
3. Visualiser le filtre afin d'y détecter ou non la présence de sang.
4. Faire un prélèvement du dialysat dans un contenant propre au niveau de la ligne dialysat rouge ou du drain de l'appareil et effectuer un test avec une bandelette de vérification « *Serim blood leak »*[1] afin de détecter la présence de sang ou non ; se référer à l'annexe 1 pour connaître les caractéristiques du produit et le mode d'utilisation. Vérifier la date d'expiration avant d'utiliser la bandelette.

   [1] *Les bandelettes de vérification « Serim blood leak » sont recommandées par le fabriquant de l'appareil d'hémodialyse pour vérifier la présence de sang dans le dialysat.*

5. **<u>Si le test est positif (PRÉSENCE DE SANG) :</u>**
   - 5.1 Arrêter le traitement sans redonner le sang à l'usager.
   - 5.2 Garder les accès perméables en injectant 10 ml de NaCL 0,9 % dans chacune des voies d'accès.
   - 5.3 Jeter le circuit extracorporel.
   - 5.4 Retirer l'appareil défectueux et aviser le technicien en génie biomédical qui doit procéder à sa réparation et désinfection.
   - 5.5 Recommencer le traitement sur un nouvel appareil, s'il reste plus de 30 minutes ou selon l'ordonnance médicale.
   - 5.6 Effectuer l'analyse sanguine suivante, lors du prochain traitement d'hémodialyse suivant la rupture de la membrane du dialyseur.

ANALYSES SANGUINES	▪ Hémoglobine (Hb) ▪ Hématocrite (Ht)

6. **<u>Si le test est négatif (PAS DE PRÉSENCE DE SANG)</u>**
   - 6.1 Valider si la présence d'air dans le dialysat est reliée au déclenchement de l'alarme.

     Si présence d'air :

     - mettre en circuit fermé afin d'éliminer l'air du circuit et
     - augmenter le débit du dialysat (si possible) en circuit fermé pour 5 minutes, puis, revenir au débit prescrit.

6.2 Si l'alarme « fuite de sang » ou « détection de sang » réapparaît, prendre un nouvel appareil et appliquer les étapes 5.1 à 5.6.

7. Rédiger les notes au dossier et ajuster le plan thérapeutique infirmier (PTI) s'il y a lieu.

Note : Lors du prochain traitement d'hémodialyse, aviser le néphrologue du résultat Hb-Ht effectué.

10. Références

Sato, M., Morita, H., Ema, H., Yamaguchi, M., & Amano, I. (2006). Effect of different dialyzer membranes on cutaneous microcirculation during hemodialysis. Clinical Nephrology, 66(6), 426-432.

Zhang, L., Liu, W., Cui, H., Ji, Y., Zhang, I., & Liu, H. (2011). Differences in bio-incompatibility among four biocompatible dialyzer membranes using in maintenance hemodialysis patients. Renal Failure Journal, 33(7), 682-691.

ANNEXE 1

INITIER LA PROCÉDURE EN CAS DE RUPTURE DE MEMBRANE D'UN DIALYSEUR EN HÉMODIALYSE

PRODUCT PROFILE

Serim®

GUARDIAN™ BLOOD LEAK TEST STRIPS

WHAT does this product do?

Serim® GUARDIAN™ Blood Leak Test Strips give a qualitative indication of the presence of blood in dialysate to assist in differentiating an actual blood leak from a false alarm.

WHY should I use this product?

The blood leak alarm may be triggered by air in the dialysate flow path, a dirty light source or photoelectric cell or by a malfunctioning detector system as well as an actual blood leak in the dialyzer membrane. Serim GUARDIAN Blood Leak Test Strips confirm that the alarm was due to an actual blood leak and avoids unnecessary interruption of the hemodialysis procedure.

AAMI recommends that dialysis machine blood leak detectors on the dialysis machine activate an alarm if blood escapes through the membrane at a rate of 0.35 mL/minute or more.[1] This leak rate calculates to a level of 5.5 mg/dL of hemoglobin in the dialysate (assuming a hematocrit of 25% and a dialysate flow of 0.5 L/minute). Serim GUARDIAN Blood Leak Test Strips are more sensitive than the AAMI- recommended setting for blood leak detectors; the test strips yield positive readings at 1.5 mg/dL hemoglobin. This increased sensitivity provides a safety margin, thereby protecting the patient against blood loss.



WHERE do I use this product?

Test the dialysate that exits from the dialyzer or test dialysate waste fluid collected from the dialysate drain line.

WHEN do I use this product?

Whenever the blood leak detector alarms, use Serim GUARDIAN Blood Leak Test Strips to verify the presence of blood in the dialysate.[2]

HOW to use this product?

Serim GUARDIAN Blood Leak Test Strips are supplied in ready-to-use form. When placed in contact with the sample according to the directions for use (see below), the indicator pad changes color in the presence of blood.

Ordering Information

Serim GUARDIAN Blood Leak Test Strips:
- Product Code 5119C contains 2 bottles with 25 strips per bottle.

Test Method	Immersion	Stream
Dialysate sample	Using a clean container, collect a dialysate sample from the dialysate drain line	Remove the line where the dialysate exits and allow it to run out in a slow stream
Test Strip Technique	Immerse indicator pad into dialysate sample and remove immediately	Wet the indicator pad of the test strip by placing the pad into the stream of dialysate for 1 second or less
Results	After 60 seconds, compare the color of the indicator pad to the color blocks on the bottle label	

Store bottles of Serim GUARDIAN Blood Leak Test Strips at temperatures between 15°- 30°C (59°- 86°F).
The lot number and expiration date are printed on the bottom of each bottle.

PRODUCT PROFILE

Related Products:

Serim GUARDIAN Bicarb pH II Test Kit (Product Code 5116A) assists in assuring dialysate quality by indicating the pH of concentrated bicarbonate solution or the final dialysate mixture of bicarbonate concentrate, acid concentrate and water.

SERIM GUARDIAN BLOOD LEAK TEST STRIPS

Features	Benefits
Ready-to-use strips	▪ No preparation or mixing of reagents ▪ No accessories, calibration or instruments needed ▪ No glass vials or sharps needed
Labeled specifically for dialysis use[3]	▪ No need to qualify an "off-label" test for dialysis use ▪ No need to monitor changes in product performance from lot-to-lot
Simple to interpret color blocks	▪ Accurate and consistent results minimize variation between readers ▪ Color of indicator pad is directly compared to color blocks on bottle label ▪ Simple to interpret color change
Convenient packaging	▪ No waste of strips even for units with a low frequency blood leak alarms
Sensitivity for positive color block set at 1.5 mg/dL vs. machine alarm sensitivity of 5.5 mg/dL	▪ Confirms any significant blood leak, even if slightly lower than machine alarm threshold ▪ Detects the level considered critical for blood leaks
Stable product performance	▪ Performance is not affected by common constituents of dialysate
Each bottle clearly labeled with: ▪ Lot number ▪ Expiration date	▪ Traceability of product from manufacturing to final use ▪ Leaves no doubt as to the age or integrity of the product
Simple procedure	▪ Eliminates reliance on inaccurate visual examination of dialysate for blood
Quick, qualitative results in 60 seconds	▪ Decision as to whether to stop or continue dialysis procedure can be made quickly
Test strip can be immersed into sample or held in sample stream	▪ Maximum convenience for user, no matter where a proper sample is most easily obtained

References:

1. AAMI Standards and Recommended Practices, Dialysis, 2008 Edition, *RD5 – Hemodialysis systems*, Association for the Advancement of Medical Instrumentation. Arlington, Virginia.
2. NANT Dialysis Technology – A Manual for Dialysis Technicians, 2 Edition (2000), pg 76. National Association of Nephrology Technicians/Technologists, Dayton, OH.
3. *Proper mechanisms for assuring disinfectant concentrations for use in hemodialysis.* Nephrol News Issues. 1999 Jun;13(6):18, 23, 27. Arduino MJ.

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Serim®

GUARDIAN™ BLOOD LEAK TEST STRIPS

Test for blood in dialysate

DESCRIPTION

Serim® GUARDIAN™ BLOOD LEAK Test Strips (Product Code 5119C) provide a rapid method to test dialysate for blood if a dialyzer membrane leak is suspected during the hemodialysis procedure.

The Association for Advancement of Medical Instrumentation[1] (AAMI) recommends that blood leak monitors on the dialysis machine activate an alarm if blood escapes through the membrane at a rate of 0.35 mL/minute or more. This leak rate calculates to a level of 5.5 mg/dL of hemoglobin in the dialysate (assuming a hematocrit of 25% and a dialysate flow of 0.5 L/minute). **Serim GUARDIAN BLOOD LEAK** Test Strips are more sensitive than the AAMI recommended setting for blood leak monitors; the test strips yield positive readings at 1.5 mg/dL of hemoglobin. This increased sensitivity provides a safety margin, thereby protecting the patient against blood loss.

The test can assist in differentiating an actual blood leak from a false alarm to avoid unnecessary interruption of the hemodialysis procedure.

CHEMICAL PRINCIPLES OF THE TEST

Serim GUARDIAN BLOOD LEAK Test Strip chemistry is based on the peroxidase-like activity of hemoglobin. A reaction between an oxidant and a chromogen is catalyzed by hemoglobin to produce a green color on the yellow background of the indicator pad.

Oxidant + Chromogen —(Hemoglobin)→ Green Color

WARNINGS AND PRECAUTIONS

- Do not hold the **Serim GUARDIAN BLOOD LEAK** indicator pad in the sample or dialysate stream more than one second to avoid washing out the test strip reagents.
- Keep all unused strips in the original bottle.
- Do not remove the desiccant pack.
- Replace the cap immediately and tightly after removing a test strip; the strips must be protected from humidity.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come into contact with work surfaces that may be contaminated with potentially interfering substances.
- Do not leave the bottle or individual strips laying on the dialysis machine as the heat from the machine will degrade the reactivity of the strips.
- Do not expose the strips to vapors of strong oxidants such as chlorine.

STORAGE

- **Serim GUARDIAN BLOOD LEAK** Test Strips must be kept in the original bottle with the lid tightly closed.
- Do not remove the desiccant pack.
- Store at temperatures between 15°–30°C (59°–86°F).
- Do not use a test strip (from an opened or unopened bottle) after the expiration date.
- Lot number and expiration date printed on bottom of bottle.

DIRECTIONS

Test for blood in dialysate using either the Dip or Stream method:

Dip Method:

1. Using a clean container, collect a dialysate sample either directly from the dialyzer (by removing the line where the dialysate exits) or from the dialysate drain line.
2. Dip the indicator pad of the test strip into the sample and remove immediately.
3. Allow the test strip to react for 60 seconds.
4. Compare the color of the indicator pad to the color blocks on the bottle label.
5. Record results and discard strip according to federal, state and local regulations.

Stream Method:

1. Obtain dialysate sample directly from the dialyzer by removing the line where the dialysate exits.
2. Wet the indicator pad of the test strip by placing the pad briefly (1 second or less) into the dialysate stream, then remove.
3. Allow the test strip to react for 60 seconds.
4. Compare the indicator pad to the color blocks on the bottle label.
5. Record results and discard strip according to federal, state and local regulations.

NOTE: Various models of dialysis machines respond differently when the blood leak alarm is activated. Some machines cause dialysate to bypass the dialyzer. In this case there is high probability that dialysate collected from the drain will be "bypassed fluid" and will not contain blood even though the dialyzer has a leak. If the machine does not have a bypass mode, a sample of dialysate from the drain can be used. Consult the dialysis machine Operators Manual or check with the manufacturer for additional information.

RESULTS

Serim GUARDIAN BLOOD LEAK Test Strips are designed to indicate the presence or absence of blood in dialysate. **At the 60-second reaction time,** compare the color of the indicator pad to the color chart on the bottle label to determine the relative amount of blood present.

- **Negative –** if the indicator pad is equal to or lighter than the Negative color block, no blood is present in the dialysate.
- **Positive –** if the indicator pad is equal to or darker than the Positive color block, a significant blood leak is indicated.

Very small leaks may yield colors between the Negative and Positive color blocks. Non-hemolyzed blood may cause a spotted color pattern to develop on the indicator pad. A small leak may seal, however close monitoring of the dialyzer is recommended.

NOTE: Indicator pads can become darker if the reaction time is extended beyond 60 seconds; therefore it is important to read the results of the test at 60 seconds.

QUALITY CONTROL

Implementing the routine use of Quality Control solutions will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that is deteriorated due to improper storage or handling. Each facility should establish its own Quality Control procedures.

Performance of **Serim GUARDIAN BLOOD LEAK** Test Strips can be confirmed by testing known positive and negative solutions as follows:

- **Positive Control Solution –** Prepare a Positive Control Solution by mixing one drop of whole blood with one to two milliliters of dialysate. Test the solution according to the DIRECTIONS section of this insert. The indicator pad should develop a color equal to or darker than the Positive color block on the bottle label.
- **Negative Control Solution –** Use a sample of dialysate that has not been exposed to blood. Test the solution according to the DIRECTIONS section of this insert. The indicator pad should develop a color equal to or lighter than the Negative color block on the bottle label.

If unexpected results are obtained, call SERIM at 1-800-542-4670 or contact your local SERIM Representative.

PERFORMANCE CHARACTERISTICS

The performance characteristics of **Serim GUARDIAN BLOOD LEAK** Test Strips are based on analytical studies using suspensions of human red blood cells in acid/bicarbonate buffer. Hemoglobin in red blood cell suspensions was measured by the Drabkin spectrophotometric method.[2]

Studies in which the strip readers were unaware of the composition of the test samples showed that positive readings were obtained consistently with red blood cell suspensions containing 1.5 mg/dL hemoglobin. This corresponds to a blood leak rate below the recommended AAMI standard of 0.35 mL/minute.[1]

Sensitivity and accuracy of the test depends on variability in color perception, lighting conditions and the possible presence of interfering substances.

LIMITATIONS

- **Serim GUARDIAN BLOOD LEAK** Test Strips should be read 60 seconds after sample application. Reading in less than 50 seconds can cause false negative readings. Also, false positive readings can be obtained when the read time is greater than 70 seconds.
- The test will yield a positive reaction with any substance which will oxidize the chromogen directly (such as sodium hypochlorite and chlorine). However, chlorine levels at which a false positive reaction would occur far exceeds the AAMI maximum recommended residual level of 0.5 ppm.[3] (Positive reactions occur only at chlorine levels greater than 5 ppm).
- Hydrogen peroxide at 5000 ppm in acid/bicarbonate buffer yielded negative results.
- Typical components of dialysis buffers, such as glucose, calcium chloride, sodium chloride, potassium chloride, sodium bicarbonate and magnesium chloride do not interfere with the test.
- The test yielded negative results in acid/bicarbonate buffers at pH 6.0, 7.4 and 8.4. Adding blood, at 1.5 mg/dL hemoglobin, to the buffers yielded positive results.

REFERENCES

[1] AAMI Standards and Recommended Practices: Dialysis, 2008 Edition. American National Standard, ANSI/AAMI RD5:2003/(R)2008, Hemodialysis Systems, page 6.
[2] RJ Eilers, Notification of final adoption of an International method and standard solution for hemoglobinometry; specifications for preparation of standard solution. Am J Clin Pathol 47:212 (1967).
[3] AAMI Standards and Recommended Practices: Dialysis, 2008 Edition. American National Standard, ANSI/AAMI RD62:2006, Water treatment equipment for hemodialysis applications, page 5.

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Processus de recommandation		
Recommandé par le(s) chef(s) de départements médicaux	Dre Élise Gilbert Chef médical de la médecine spécialisée	2018-03-28
Recommandé par l'(les) instance(s) (si pertinence seulement)	Mélanie Caron, présidente Comité de pharmacologie	2018-03-29

Historique du document		
Approuvé par	Dr Gaétan Filion, président Conseil des médecins, dentistes et pharmaciens	2018-04-10

Annulation d'outils cliniques existants

En date d'entrée en vigueur mentionnée, cette ordonnance collective vient annuler les outils cliniques suivants :

Installation(s)	**Annulation**