

DESCRIPTION DU DISPOSITIF

Les dispositifs comprennent une poche possédant une ou deux voies d'entrée selon les références. Chaque poche contient un certain volume de solution de conservation des plaquettes SSP ou SSP+ selon la composition suivante:

- Composition SSP:** Na₂citrate 2H₂O: 2.94g, Naacetate 3H₂O: 4.08g, NaCl: 6.75g, Eau PI 1000 ml, pH 7.2
- Composition SSP+:** Na₂citrate 2H₂O: 3.18g, Naacetate 3H₂O: 4.42g, NaH₂PO₄ 2H₂O: 1.05g, Na₂HPO₄ 3.05g, KCl: 0.37g, MgCl₂ 6H₂O: 0.30g, NaCl: 4.05g, Eau PI 1000 ml, pH 7.2

La poche contenant les solutions est en non PVC. Le PVC des tubulures est plastifié par du DEHP. Les produits biologiques sont aseptés et/ou circulants dans le dispositif prevent contenant des phalates.

INDICATIONS

Les solutions de conservation des plaquettes SSP et SSP+ sont destinées au remplacement partiel du plasma lors de la préparation et la conservation de concentrés de plaquettes issus de buffy-coats ou d'aphérèses. Les ratios recommandés sont les suivants: jusqu'à 70% SSP / 30% plasma, jusqu'à 80% SSP+ / 20% plasma. Ces solutions permettent une conservation des plaquettes à 22 °C ± 2 °C sous agitation douce, jusqu'à 5 jours (SSP) ou 7 jours (SSP+) après le prélèvement, selon les autorisations locales.

CONTRE INDICATIONS

Il n'y a pas d'effets secondaires connus liés à l'utilisation des solutions SSP ou SSP+.

PRECAUTIONS D'UTILISATION

- Vérifier l'intégrité du dispositif et de l'emballage avant utilisation
- Utiliser le dispositif à une température comprise entre 18° et 24°C
- Ne pas stocker le dispositif à une température supérieure à 35°C
- Éviter le contact avec des objets pointus ou tranchants
- Ne pas utiliser si le suremballage et/ou le dispositif présente(n) des signes visibles de détérioration
- Ne pas utiliser si la solution est trouble
- Ne pas utiliser de prise d'air pour la transfusion des plaquettes
- Ne jamais perfuser directement la solution
- Le dispositif doit être utilisé avec d'autres dispositifs possédant des connexions conformes aux normes: ISO 5942.
- Ne pas nettoyer le dispositif. Le risque associé à une stérilisation serait une contamination. De plus, la quantité de solution restante serait insuffisante.

INSTRUCTIONS D'UTILISATION

- Pool avec un dispositif piéuvre (utilisation de 4 à 6 Buffy-Coats)**
 - Réaliser une connexion stérile entre chaque tubulure des buffy-coats et chaque tubulure du dispositif piéuvre.
 - Connecter la solution SSP/SSP+ à la dernière tubulure du dispositif par une connexion stérile.
 - Suspendre au même niveau toutes les poches de buffy-coat, et plus en hauteur la poche de solution SSP ou SSP+.
 - Close the clamp above the pooling bag and then allow the SSP or SSP+ solution to drain into each buffy-coat.
 - Laisser les buffy-coats s'écouler dans la poche de recueil.
 - Fermer le clamp ou dessus de la poche de mélange et laisser la solution SSP ou SSP+ s'écouler dans chaque poche de buffy-coat.
 - Agiter afin de récupérer un maximum de buffy-coat. Ouvrir le clamp, laisser le mélange s'écouler.
 - Disconnect the dispositif piéuvre et suivre la procédure habituelle pour la préparation d'un concentré de plaquettes.

Pool en cascade (utilisation de 4 à 6 Buffy-Coats)

- Connecter par stérile connection la tubulure de la poche de solution SSP ou SSP+ à la ligne de prélèvement de la première poche de buffy-coat.
- Réaliser une connexion stérile entre la tubulure de plasma de la première poche de buffy-coat (tubule équipée d'un over-circuit) et la tubulure de la ligne de prélèvement de la deuxième poche de buffy-coat.
- Then make a sterile connection between the second buffy-coat and the third buffy-coat. Repeat the operation with each buffy-coat until a maximum of 6 buffy-coats are pooled.
- Opérer la tubulure de la ligne de plasma de la dernière poche de buffy-coat à un système de recueil des plaquettes.
- Suspendre verticalement l'ensemble (en dessous de la poche de solution SSP ou SSP+). Laisser les buffy-coats s'écouler dans la poche de mélange.
- Utiliser la solution SSP ou SSP+ pour rincer les poches feu après l'autre.
- Disconnect the dispositif et suivre la procédure habituelle pour la préparation d'un concentré de plaquettes.

Aphérèse

- Connecter le dispositif d'aphérèse, la solution SSP ou SSP+ peut être utilisée en tant que solution de substitution d'une partie du plasma dans le concentré de plaquettes.
- Connecter la solution à l'aide du luer ou kit d'aphérèse.
- Casser le luer scellable en pivotant le connecteur par un mouvement de va-et-vient à 90° jusqu'à entendre un "craac" (voir schéma (A)).
- Plier ensuite le luer à 180° afin d'obliger la pièce scellable en forme de flèche à glisser dans la tube souple vers l'entrée de la poche, en l'éloignant ainsi de la base (B). Si ce n'est pas le cas, répéter l'étape 3. B.
- Suspendre la poche de solution
- Suivre le protocole d'aphérèse valide dans votre établissement. Laisser s'écouler la quantité de solution de conservation adéquate dans la poche de plaquettes et mélanger doucement.

PRECAUTIONS POUR LA MISE AU REBUT

La mise au rebut des poches doit être effectuée selon les règles applicables pour les déchets biologiques potentiellement contaminés.

DESCRIPTION OF THE DEVICE

The devices include a bag designed with one or two connection modes, according to the references. Each bag contains a certain volume of platelet additive solution SSP or SSP+ according to following composition:

- Composition SSP:** Na₂citrate 2H₂O: 2.94g, Naacetate 3H₂O: 4.08g, NaCl: 6.75g, Water for Injection 1000 ml, pH 7.2
- Composition SSP+:** Na₂citrate 2H₂O: 3.18g, Naacetate 3H₂O: 4.42g, NaH₂PO₄ 2H₂O: 1.05g, Na₂HPO₄ 3.05g, KCl: 0.37g, MgCl₂ 6H₂O: 0.30g, NaCl: 4.05g, Water for Injection 1000 ml, pH 7.2

The bag containing the solutions is non-PVC. The PVC of the tubings is DEHP plasticized. The biological products are not-PVC or circulating in the device could prevent container des phalates.

INDICATIONS

The platelet additive solutions SSP and SSP+ are designed to partially replace plasma in the preparation and storage of buffy-coat derived platelet concentrates or apheresis platelet units. The recommended ratios are as follows: up to 70% SSP / 30% plasma, up to 80% SSP+ / 20% plasma. These solutions enable platelets to be stored at 22 °C ± 2 °C, under gentle agitation, for up to 5 days (SSP) or 7 days (SSP+) following collection and according to local regulations.

SIDE EFFECTS

There are no known side effects with the use of SSP or SSP+.

WARNING

- Verify the integrity of the device and the overwrap before use.
- Use the device at a temperature between 18° and 24 °C
- Do not store the device at a temperature above 35 °C
- Do not use sharp objects.
- Do not use if the overwrap or the device show any visible signs of deterioration.
- Do not use if the solution is cloudy.
- Do not use for the transfusion of platelets.
- Do not directly infuse the solution.
- The device must be used with other approved devices including connectors complying with current standards: ISO 5942.
- Do not reuse the device, as there could be a risk of contamination. And additionally, the remaining quantity of solution might be insufficient.

INSTRUCTIONS FOR USE

- Manifold pooling (use of 4 to 6 Buffy-Coats)**
 - Make a sterile connection between each buffy-coat tubing and each end-line tubing of the manifold device.
 - Connect by sterile connection the SSP or SSP+ bag tubing to the remaining manifold set end-tubing.
 - Hang all the buffy-coat bags at the same level and the SSP or SSP+ bag on a higher level.
 - Allow the buffy-coats to drain into the pooling bag.
 - Close the clamp above the pooling bag and then allow the SSP or SSP+ solution to drain into each buffy-coat.
 - Agitate in order to recover a maximum of buffy-coat & open the clamp, allow the SSP/SSP+ solution to drain into the pooling bag.
 - Remove the manifold set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

Cascade pooling (4-6 Buffy Coats)

- Connect by sterile connection the SSP or SSP+ bag tubing to the bleed line of the first buffy-coat bag in the train.
- Make a sterile connection between the buffy-coat plasma line (tube equipped with a breakaway cannula) of the first buffy-coat bag and the bleed line of the second buffy-coat.
- Then make a sterile connection between the second buffy-coat and the third buffy-coat. Repeat the operation with each buffy-coat until a maximum of 6 buffy-coats are pooled.
- Operate the tubing of the plasma line of the last buffy-coat bag to a platelet recovery set.
- Hang the chain vertically by suspending the SSP or SSP+ bag with the chain of buffy-coats underneath. Allow the buffy-coats to drain into the pooling bag.
- Use the SSP or SSP+ solution to drain one bag after each other.
- Remove the set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

Apheresis

- Connected to the apheresis set, the SSP or SSP+ solution can be used as a substitution solution for a part of the plasma in platelet concentrates.
- Connect the Additive Solution with the luer connector to the apheresis set.
- Break the breakable connector in the Additive Solution line by moving the connector back and forth 90° until an audible "snaps" sound is heard in both directions (see drawing (A)).
- Band tubing 180° to force the arrow piece of the frangible upward into the soft tubing closer to the bag opening and away from the base (B). This prevents this piece from resealing. To ensure proper flow, check to see if a gap exists between the arrow and base of the frangible (C). If not repeat step B.
- Hang the Additive Solution bag on the IV hook with the platelet product bag supported (not hanging) below.
- Follow the valid apheresis protocol of your institution. Allow the appropriate amount of storage solution to flow into the platelet product bag and mix gently.

DISCARD WARNINGS

Discard according to the local regulation(s) on the potentially dangerous biological products.

Produktbeschreibung

Das Produkt besteht aus einem Beutel, der je nach Referenz mit ein oder zwei Anschlüssen versehen ist. Jeder Beutel enthält ein definiertes Volumen der Thrombozytenkonzentrat-Additiv-Lösung (platelet additive solution) SSP oder SSP+ entsprechend folgender Zusammensetzung:

Der Beutel selbst besteht nicht aus PVC. Das PVC der Schläuche enthält den Weichmacher DEHP. Die biologischen Produkte, die darin gelagert oder damit in Berührung gekommen sind, können Phthalate enthalten.

ANWENDUNGSBEREICHE

Die Thrombozytenkonzentrat-Additiv-Lösungen SSP und SSP+ dienen zum partiellen Ersatz von Plasma bei der Herstellung und Lagerung von Thrombozytenkonzentraten, welche aus Buffy-Coats oder mittels Apherese gewonnen werden. Das empfohlene Verhältnis beträgt: bis zu 70% SSP / 30% Plasma bzw. bis zu 80% SSP+ / 20% Plasma. Diese Lösungen erlauben eine Lagerung von Thrombozyten im Agitator bei 22 °C ± 2 °C vor bis zu 5 Tagen (SSP) bzw. 7 Tagen (SSP+) nach der Spende und entsprechend den jeweiligen gesetzlichen Vorgaben.

SIDE EFFECTS

There are no known side effects with the use of SSP or SSP+.

WARNING

- Verify the integrity of the device and the overwrap before use.
- Use the device at a temperature between 18° and 24 °C
- Do not store the device at a temperature above 35 °C
- Do not use sharp objects.
- Do not use if the overwrap or the device show any visible signs of deterioration.
- Do not use if the solution is cloudy.
- Do not use for the transfusion of platelets.
- Do not directly infuse the solution.
- The device must be used with other approved devices including connectors complying with current standards: ISO 5942.
- Do not reuse the device, as there could be a risk of contamination. And additionally, the remaining quantity of solution might be insufficient.

INSTRUCTIONS FOR USE

- Manifold pooling (use of 4 to 6 Buffy-Coats)**
 - Make a sterile connection between each buffy-coat tubing and each end-line tubing of the manifold device.
 - Connect by sterile connection the SSP or SSP+ bag tubing to the remaining manifold set end-tubing.
 - Hang all the buffy-coat bags at the same level and the SSP or SSP+ bag on a higher level.
 - Allow the buffy-coats to drain into the pooling bag.
 - Close the clamp above the pooling bag and then allow the SSP or SSP+ solution to drain into each buffy-coat.
 - Agitate in order to recover a maximum of buffy-coat & open the clamp, allow the SSP/SSP+ solution to drain into the pooling bag.
 - Remove the manifold set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

GEBRAUCHSANLEITUNG

- Parallel-Pooling (4 bis 6 Buffy-Coats)**
 - Die einzelnen Buffy-Coat-Einheiten werden nebeneinander mit einem für diese Poolingmethode vorgesehenen System steril verknüpft.
 - SSP / SSP+ Beutel mit dem linken, äußeren Schlauchende des Pooling-Systems steril verbinden.
 - Alle Buffy-Coat-Beutel in gleiche Höhe hängen, SSP / SSP+ Beutel höher hängen.
 - Inhalt der einzelnen Buffy-Coat-Beutel in den Pooling-Beutel fließen lassen.
 - Alle Klappen über dem Pooling-Beutel schließen und mit der SSP oder SSP+ Lösung die Beutel unter Agitation gut spülen, um möglichst viel Buffy-Coat zu erhalten.
 - Klappen öffnen und die SSP / SSP+ Lösung in den Pooling-Beutel fließen lassen.
 - Das Pooling-Set entfernen und den Thrombozytenpool gemäß den üblichen Methoden weiterverarbeiten.

Kaskaden-Pooling (4-6 Buffy Coats)

- Connect by sterile connection the SSP or SSP+ bag tubing to the bleed line of the first buffy-coat bag in the train.
- Make a sterile connection between the buffy-coat plasma line (tube equipped with a breakaway cannula) of the first buffy-coat bag and the bleed line of the second buffy-coat.
- Then make a sterile connection between the second buffy-coat and the third buffy-coat. Repeat the operation with each buffy-coat until a maximum of 6 buffy-coats are pooled.
- Operate the tubing of the plasma line of the last buffy-coat bag to a platelet recovery set.
- Hang the chain vertically by suspending the SSP or SSP+ bag with the chain of buffy-coats underneath. Allow the buffy-coats to drain into the pooling bag.
- Use the SSP or SSP+ solution to drain one bag after each other.
- Remove the set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

Apheresis

- Connected to the apheresis set, the SSP or SSP+ solution can be used as a substitution solution for a part of the plasma in platelet concentrates.
- Connect the Additive Solution with the luer connector to the apheresis set.
- Break the breakable connector in the Additive Solution line by moving the connector back and forth 90° until an audible "snaps" sound is heard in both directions (see drawing (A)).
- Band tubing 180° to force the arrow piece of the frangible upward into the soft tubing closer to the bag opening and away from the base (B). This prevents this piece from resealing. To ensure proper flow, check to see if a gap exists between the arrow and base of the frangible (C). If not repeat step B.
- Hang the Additive Solution bag on the IV hook with the platelet product bag supported (not hanging) below.
- Follow the valid apheresis protocol of your institution. Allow the appropriate amount of storage solution to flow into the platelet product bag and mix gently.

Descrizione del dispositivo

Il dispositivo comprende un sacco provvisto di una o due modalità di connessione, a seconda delle referenze. Ciascuno sacco contiene un certo volume di soluzione additiva per piastrine SSP o SSP+ secondo la seguente composizione:

Il sacco contenente le soluzioni è in materiale non-PVC. Il PVC dei tubulativi è plastificato DEHP. I prodotti biologici conservati e/o transittori in questi dispositivi potrebbero contenere feolati.

INDICAZIONI

Le soluzioni conservate per piastrine SSP/SSP+ sono destinate alla parziale sostituzione del plasma nella preparazione e conservazione del concentrato piastrinico da buffy-coat o da aferesi. I rapporti raccomandati sono i seguenti: fino al 70% di SSP / 30% di plasma; fino al 80% di SSP+ / 20% plasma. Queste soluzioni consentono la conservazione delle piastrine a 22 °C ± 2 °C, in continua agitazione per 5 [SSP] o 7 [SSP+] giorni dall'uscita di raccolta e secondo le normative locali.

EFFETTI COLLATERALI

Non ci sono effetti indesiderati conosciuti con l'uso di SSP o SSP+.

AVVERTENZE

- Controllare l'integrità del dispositivo e dell'imballo prima dell'uso
- Utilizzare il dispositivo ad una temperatura compresa tra 18° e 24°C
- Non conservare ad una temperatura superiore ai 35°C
- Non utilizzare oggetti appuntiti.
- Non utilizzare se l'imballo o il dispositivo presentano segni evidenti di deterioramento.
- Non utilizzare se la soluzione è torbida.
- Non utilizzare per la trasfusione di piastrine.
- Non utilizzare senza i dispositivi approvati, compresi i connettori conformi ai normae ISO 5942.
- Non riutilizzare il dispositivo, poiché il rischio di contaminazione. Inoltre, la quantità rimanente di soluzione potrebbe essere insufficiente.

ISTRUZIONI D'USO

- Pool con dispositivo a piastra (4-6 Buffy-Coat)**
 - Effettuare una connessione sterile tra ogni buffy-coat e ogni raccordo del dispositivo a piastrina.
 - Connettere il tubo della soluzione SSP/SSP+ al raccordo rimanente.
 - Appendere tutte le sacche buffy-coat allo stesso livello e la sacca SSP/SSP+ ad un livello più alto.
 - Lasciar defluire i buffy-coat nella sacca di raccolta del pooling.
 - Chiudere la clamp sopra la sacca di raccolta quindi fare in modo che la soluzione SSP/SSP+ scenda in ciascuna sacca di buffy-coat.
 - Agitare per recuperare il massimo dai buffy-coat ed aprire la clamp, far scendere la soluzione SSP/SSP+ nella sacca di raccolta.
 - Das Pooling-Set entfernen und den Thrombozytenpool gemäß den üblichen Methoden weiterverarbeiten.

Pool con dispositivo a cascata (4-6 Buffy-Coat)

- Connect by sterile connection the SSP or SSP+ bag tubing to the bleed line of the first buffy-coat bag in the train.
- Make a sterile connection between the buffy-coat plasma line (tube equipped with a breakaway cannula) of the first buffy-coat bag and the bleed line of the second buffy-coat.
- Then make a sterile connection between the second buffy-coat and the third buffy-coat. Repeat the operation with each buffy-coat until a maximum of 6 buffy-coats are pooled.
- Operate the tubing of the plasma line of the last buffy-coat bag to a platelet recovery set.
- Hang the chain vertically by suspending the SSP or SSP+ bag with the chain of buffy-coats underneath. Allow the buffy-coats to drain into the pooling bag.
- Use the SSP or SSP+ solution to drain one bag after each other.
- Remove the set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

Aferese

- Quando il connettore al kit di aferesi, la soluzione SSP/SSP+ può essere utilizzata come un sostituto del plasma nel concentrato di piastrine.
- Connettere l'Additivo Soluzione al luer connector to the apheresis set.
- Break the breakable connector in the Additive Solution line by moving the connector back and forth 90° until an audible "snaps" sound is heard in both directions (see drawing (A)).
- Band tubing 180° to force the arrow piece of the frangible upward into the soft tubing closer to the bag opening and away from the base (B). This prevents this piece from resealing. To ensure proper flow, check to see if a gap exists between the arrow and base of the frangible (C). If not repeat step B.
- Hang the Additive Solution bag on the IV hook with the platelet product bag supported (not hanging) below.
- Follow the valid apheresis protocol of your institution. Allow the appropriate amount of storage solution to flow into the platelet product bag and mix gently.

PRECAUCOES DE UTILIZACAO

A utilização do dispositivo deve estar conforme com os procedimentos padrões para obter um concentrado de plaquetas derivado de uma pool de buffy-coat.

PRECAUCOES PARA RECEICAO

A recepção das bolsas deve ser efectuado segundo as regras aplicáveis para os resíduos biológicos potencialmente contaminados.

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APRESENTAZAO DO DISPOSITIVO

O dispositivo possuem uma bolsa de uma ou duas vias de entrada segundo as referências. Cada bolsa contém um certo volume de solução de conservação das plaquetas SSP ou SSP+ segundo a composição seguinte:

O PVC está em conformidade com o Farmacópio Europeu. O plastificante é o DEHP. Os produtos biológicos armazenados e/ou que circulam nestes dispositivos podem conter feólato.

INDICACOES

As soluções de conservação das plaquetas SSP e SSP+ estão destinadas à substituição parcial do plasma quando da preparação de do conservação de concentrados de plaquetas provenientes de buffy-coats ou de aferese. Os ratios recomendados são os seguintes: até 70% SSP / 30% plasma, até 80% SSP+ / 20% plasma. Estas soluções permitem uma conservação das plaquetas a 22 °C ± 2 °C sob agitação suave, até 5 dias (SSP) ou 7 dias (SSP+) após a coleta, segundo as autorizações locais.

EFETOS SECUNDARIOS

Não são conhecidos quaisquer efeitos secundários com o uso da SSP/SSP+.

PRECAUCOES DE UTILIZACAO

- Verificar a integridade do dispositivo e do embalagem antes da utilização
- Utilizar o dispositivo a uma temperatura compreendida entre 18° e 24°C
- NO ARMARZENAR A MACOPHARMA SSP/SSP+ ACIMA DOS 35 °C
- Evitar o contacto com objectos bicudos ou cortantes
- NO UTILIZAR SE O PRODUTO MOSTRAR SINAIS VISIVEIS DE DETERIORACAO
- NO UTILIZAR SE A SOLUCAO ESTIVER TORBIDA
- Não utilizar de tomada de do para o transfusão das plaquetas
- NO INFUNDIR A SOLUCAO DIRECTAMENTE
- O dispositivo deve essere utilizzato con outros dispositivos possiendo conexoes conformes às normas ISO 5942.
- NO REUTILIZAR O SACCO POIS PODE HAVER RISCO DE CONTAMINACAO
- Para além disso, a quantidade de solução restante seria insuficiente

INSTRUÇÕES DE USO

- UFUTE ZA UPOTREBU**
 - Mnogostruko "pooliranje" (4-6 "Buffy-Coat"-a)**
 - Čsaatkožastava sterilno se SSP vagy SSP+ zsák csövezetékét a lenmaradó manifold szerelék-csővéghöz.
 - Ákassa fel az összes buffy-coat zsákot azonos magasságra, az SSP vagy SSP+ zsákokat pedig magasabbra.
 - Hagyja, hogy a buffy-coat átfolyjon a poolozó zsákba.
 - Zárja el a szűrőt a poolozó zsák fölött, majd hagyja, hogy az SSP vagy SSP+ idát átfolyjon mindkét buffy-coat zsákba.
 - Rázza, hogy maximális buffy-coat kinyerés legyen, és nyissa ki a szűrőt engedve az SSP/SSP+ oldat átfolyását a poolozó zsákba.
 - Távolítsa el a manifold szerelék és kövesse a poolozott buffy-coat-ból származó thrombo-cyta-koncentrátum kinyeréséhez szükséges standard eljárásmentet.

Kaskádno pooliranje (4-6 Buffy Coats)

- Connect by sterile connection the SSP or SSP+ bag tubing to the bleed line of the first buffy-coat bag in the train.
- Make a sterile connection between the buffy-coat plasma line (tube equipped with a breakaway cannula) of the first buffy-coat bag and the bleed line of the second buffy-coat.
- Then make a sterile connection between the second buffy-coat and the third buffy-coat. Repeat the operation with each buffy-coat until a maximum of 6 buffy-coats are pooled.
- Operate the tubing of the plasma line of the last buffy-coat bag to a platelet recovery set.
- Hang the chain vertically by suspending the SSP or SSP+ bag with the chain of buffy-coats underneath. Allow the buffy-coats to drain into the pooling bag.
- Use the SSP or SSP+ solution to drain one bag after each other.
- Remove the set and then follow standard procedures to obtain a pooled buffy-coat derived platelet concentrate.

Aferese

- Quando conectado ao kit de aferese, a solução SSP/ SSP+ pode ser usada para substituir um parte do plasma no concentrado de plaquetas.
- Conecte a solução Aditivo com o conector luer ao kit de aferese.
- Quebre o conector da linha de Solução Aditiva, movendo-o para frente e para trás, o 90° até ouvir um "estalo" em ambas as direções (ver esquema (A)).
- Dobre depois o tubo a 180° para obrigá-lo a pressar-se em forma de seta e inserir no tubo Bevel até direções da entrada do tubo, afastando-o assim da base (B).
- Por garantir um fluxo corrente, verifique a existência de espaço entre o círculo de introdução (C) e o base do círculo; se não houver, repita o passo B.
- Pendure o Aditivo SSP/SSP+ numa praxe fixa um saco após o outro.
- Remover o kit e depois seguir os procedimentos padrão para obter um concentrado de plaquetas derivado de uma pool de buffy-coat.

PRECAUCOES PARA RECEICAO

A recepção das bolsas deve ser efectuado segundo as regras aplicáveis para os resíduos biológicos potencialmente contaminados.

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Opis proizvoda

Medicinski proizvod sadrži vrećicu sa jednim ili dva sploja, ovisno o referenci. Svaka vrećica sadrži određeni volumen aditivne otopine za trombocite SSP ou SSP+ sljedećeg sastava:

Proizvod je u skladu s lokalnom propisima.

UPOZORENJE

- Prije upotrebe provjeriti cjelovitost proizvoda i vanjskog omota.
- Koristiti proizvod na temperaturi između 18° i 24°C.
- Ne čuvati na temperaturi iznad 35°C.
- Ne koristiti otvore predate.
- Ne koristiti ako na vanjskom omotu ili proizvodu postoje vidljivi znaci oštećenja.
- Ne koristiti ako je otopina zamućena.
- Ne ispuštivati direktno transfuzije trombocita.
- Ne infundirati samu otopinu.
- Proizvod mora biti korišten u skladu sa ostalim proizvodima uključujući proizvode koji su u skladu sa standardim ISO 5942.
- Proizved ne koristiti ponovno, jer postoji mogućnost kontaminacije i preostala količina otopine može biti nedovoljna.

UPOZORENJE

- Verificar a integridade do dispositivo e do embalagem antes da utilização
- Utilizar o dispositivo a uma temperatura compreendida entre 18° e 24°C
- NO ARMARZENAR A MACOPHARMA SSP/SSP+ ACIMA DOS 35 °C
- Evitar o contacto com objectos bicudos ou cortantes
- NO UTILIZAR SE O PRODUTO MOSTRAR SINAIS VISIVEIS DE DETERIORACAO
- NO UTILIZAR SE A SOLUCAO ESTIVER TORBIDA
- Não utilizar de tomada de do para o transfusão das plaquetas
- NO INFUNDIR A SOLUCAO DIRECTAMENTE
- O dispositivo deve essere utilizzato con outros dispositivos possiendo conexoes conformes às normas ISO 5942.
- NO REUTILIZAR O SACCO POIS PODE HAVER RISCO DE CONTAMINACAO
- Para além disso, a quantidade de solução restante seria insuficiente

INSTRUÇÕES DE USO

- UFUTE ZA UPOTREBU**
 - Mnogostruko "pooliranje" (4-6 "Buffy-Coat"-a)**
 - Čsaatkožastava sterilno se SSP vagy SSP+ zsák csövezetékét a lenmaradó manifold szerelék-csővéghöz.
 - Ákassa fel az összes buffy-coat zsákot azonos magasságra, az SSP vagy SSP+ zsákokat pedig magasabbra.
 - Hagyja, hogy a buffy-coat átfolyjon a poolozó zsákba.
 - Zárja el a szűrőt a poolozó zsák fölött, majd hagyja, hogy az SSP vagy SSP+ idát átfolyjon mindkét buffy-coat zsákba.
 - Rázza, hogy maximális buffy-coat kinyerés legyen, és nyissa ki a szűrőt engedve az SSP/SSP+ oldat átfolyását a poolozó zsákba.
 - Távolítsa el a manifold szerelék és kövesse a poolozott buffy-coat-ból származó thrombo-cyta-koncentrátum kinyeréséhez szükséges standard eljárásmentet.

