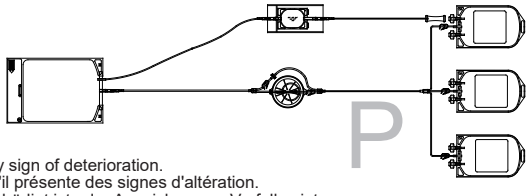
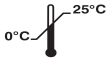
INTERCEPT BLOOD SYSTEM




en - Do not use if the product, its sterile barrier system or its packaging is damaged or shows any sign of deterioration.
fr - Ne pas utiliser si le produit, sa barrière de stérilité ou son emballage a été endommagé ou s'il présente des signes d'altération.
de - Nicht verwenden, wenn das Produkt, die Sterilverpackung oder dessen Umverpackung beschädigt ist oder Anzeichen von Verfall zeigt.
nl - Niet gebruiken indien het product, de steriele barrière of de verpakking beschadigd is of tekenen van beschadiging vertoont.
it - Non utilizzare se il prodotto, la sua barriera sterile o il suo confezionamento sono danneggiati o mostrano segni di deterioramento.
es - No usar si el producto, su barrera estéril o su envase está dañado o muestra cualquier signo de deterioro.
pt - Não utilizar caso ou produto, a sua proteção estéril ou a sua embalagem estejam danificados ou apresentem quaisquer sinais de deterioração.
sv - Används ej om produkten, dess sterilbarriär eller dess förpackning är skadad eller visar några tecken på avvikelse.
da - Må ikke anvendes hvis produktet, sterilbarriererne eller pakningerne er beskadigede eller der er tegn på brud.
fi - Älä käytä jos tuotteen steriilisuojat ovat irti tai pakkaus on silminnähden vahingoittunut.
no - Må ikke brukes dersom pruduktet, dets sterilbarriere eller emballasje er skadet eller viser tegn til forringelse.
el - Μη χρησιμοποιείτε, εάν το προϊόν, το στείρο σύστημα φραγμού του ή η συσκευασία του είναι κατεστραμμένα ή παρουσιάζει οποιοδήποτε σημάδι φθοράς.
cs - Nepoužívejte , jestliže je výrobek, jeho sterilní barierový systém nebo obal poškozen, nebo vykazuje-li jakékoli známky porušení.
ru - Не использовать, если нарушена целостность продукта, системы стерильной преграды, упаковки или при наличии видимых признаков повреждения.
pl - Nie używać jeżeli produkt, jego system bariery sterylnej lub jego opakowanie jest zniszczone lub wykazuje jakiekolwiek oznaki uszkodzenia.
tr - Ürün, steril bariyer sistemi veya ambalaj zarar görmüşse ya da bozulme belirtisi varsa kullanmayınız.
sl - Ne uporabite, če so izdelek, sterilni zaščitni sistem ali ovojnina poškodovani ali kažejo znake poslabšanja kakovosti.
kk - Зарарсыздандыруды қорғау жүйесінің немесе қаптамасының зақымданғаның немесе нашарлауының белгілерін көрсеңіз, өнімді қолданбаңыз.
hr - Ne upotrebljavati ako su proizvod, sterilni zaštitni sustav ili ambalaža oštećeni ili ako pokazuju bilo kakav znak pogoršanja kakvoće.
et - Ärge kasutage, kui toode, selle steriilne barjäärisüsteem või pakend on vigastatud või nähtavate riknemismärkidega.
lv - Nelietojiet izstrādājumu, ja izstrādājums, tā sterilā barjersistēma vai iepakojums ir bojāts, vai ir redzamas jebkādas bojājuma pazīmes.
uk - Не використовувати, якщо порушено цілісність продукту, його системи стерильної перепони чи упаковки, або є будь-яка ознака наявного пошкодження.
sk - Nepoužívajte, ak je výrobok, jeho sterilná bariéra alebo jeho obal poškodený alebo vykazuje známky porušenia.
sr - Ne koristiti ako su proizvod, sistem sterilne barijere ili pakovanje oštećeni ili na njima postoje bilo kakvi znaci propadanja.




en - Do not freeze. Do not store above 25°C.
fr - Ne pas congeler. Ne pas stocker à plus de 25°C.
de - Nicht einfrieren. Nicht über 25°C lagern.
nl - Niet invriezen. Niet bewaren boven 25°C.
it - Non congelare. Non conservare a temperature superiori a 25°C.
es - No congelar. No almacenar por encima de 25°C.
pt - Não congelar. Não guardar acima de 25°C.
sv - Får ej frysa. Förvaras ej över 25°C.
da - Må ikke fryses. Må ikke opbevares over 25°C.
fi - Ei saa jäätyä. Älä säilytä yli 25°C.
no - Må ikke fryses. Må ikke lagres i temperatur over 25°C.
el - Μην καταψύχετε. Μην αποθηκεύετε σε θερμοκρασία άνω των 25°C.
cs - Nezmrazujte. Neskladujte nad 25°C.
ru - Не замораживать. Не хранить при температуре выше 25°C.
pl - Nie zamrażać. Nie przechowywać w temperaturze powyżej 25°C.
tr - Dondurulmamalıdır. 25 C'nin üzerinde saklamayınız.
sl - Ne zamrznite. Ne hranite pri temperaturi nad 25°C.
kk - Тоңазытпаңыз. 25°C-тан жоғары температурада сақтамаңыз.
hr - Ne smrzavati. Čuvati na temperaturi ispod 25 °C.
et - Mitte hoida sügavkülmas. Mitte hoida temperatuuril üle 25 °C.
lv - Nesasaldēt. Uzglabāt līdz 25°C temperatūrā.
uk - Не заморожувати. Не зберігати при температурі вище 25 °C.
sk - Nezmrazujte. Neskladujte pri teplote nad 25°C.
sr - Ne zamrzavati. Ne čuvati na temperaturama iznad 25°C.

P

en - For plasma processing
fr - Pour le traitement du plasma
de - Für Plasma Behandlung
nl - Voor plasmaverwerking
it - Per il trattamento del plasma
es - Para procesamiento de plasma
pt - Para processamento de plasma
sv - För plasma beredning
da - Til plasma fremstilling
fi - Plasmankäsittelysetti
no - For plasma fremstilling
el - για επεξεργασία πλάσματος
cs - Pro zpracování plazmy
ru - Для обработки плазмы
pl - Do przetwarzania osocza
tr - Plazmayı işlemek için
sl - Za predelavo plazme
kk - Плазманы өңдеу үшін
hr - Za obradu plazme
et - Plasma töötlemiseks
lv - Plazmas apstrādei
uk - Для обробки плазми
sk - Na spracovanie plazmy
sr - Za obradu plazme

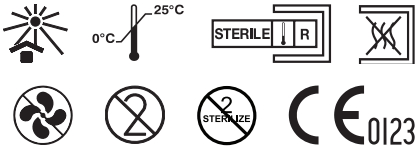
en - Plasma storage container
fr - Poche de conservation du plasma
de - Plasmalagerungsbeutel
nl - Bewaarzak voor plasma
it - Sacca per la conservazione del plasma
es - Recipiente de almacenamiento de plasma
pt - Recipiente de conservação de plasma
sv - Plasmaförvaringspåse
da - Plasmaopbevaringspose
fi - Plasman säilytyspussi
no - Lagringspose for plasma
el - Περιέκτης αποθήκευσης πλάσματος
cs - Zásobník na skladování plazmy
ru - Контейнер для хранения плазмы
pl - Pojemnik do przechowywania osocza
tr - Plazma saklama kabı
sl - Shranjevalni vsebnik za plazmo
kk - Плазманы сақтау ыдысы
hr - Spremnik za pohranu plazme
et - Plasma säilituskott
lv - Plazmas glabāšanas konteiners
uk - Контейнер для зберігання плазми
sk - Zásobník na skladovanie plazmy
sr - Posuda za čuvanje plazme

en - Refer to Instructions for Use
fr - Consulter la notice
de - Siehe Gebrauchsanleitung
nl - Raadpleeg de gebruiksaanwijzing
it - Consultare le istruzioni per l'uso
es - Consulte las instrucciones de uso
pt - Consultar as instruções de utilização
sv - Se bruksanvisningen
da - Se brugsanvisningen
fi - Katso käyttöhjeet
no - Se bruksanvisningen
el - Συμβουλευτείτε τις οδηγίες χρήσης
cs - Viz návod k použití
ru - См. инструкцию по применению
pl - Proszę zapoznać się z instrukcją użytkowania
tr - Kullanma talimatına başvurun
sl - Pozor: Glejte navodilo za uporabo!
kk - Пайдалану нұсқаулықтарын қараңыз
hr - Vidi upute za uporabu
et - Tutvuge kasutusjuhendiga
lv - Skatiet lietošanas instrukciju
uk - Звертайтесь до вказівок із використання
sk - Prečítajte si návod na použitie
sr - Pogledajte uputstvo za upotrebu

**Cerus Corporation**
1220 Concord Avenue
Concord, CA 94520 USA

EC REP

**Cerus Europe B.V.**
Stationsstraat 79-D
3811 MH Amersfoort
The Netherlands



INTERCEPT BLOOD SYSTEM

en - Protect from direct sunlight and strong UVA light source.
fr - Protéger des rayons directs du soleil et d'une source puissante de rayons U.V.A.
de - Vor direkter Sonneneinstrahlung und starker UVA-Strahlung schützen.
nl - Beschermen tegen direct zonlicht en krachtige bronnen van uva-licht.
it - Proteggere dalla luce solare diretta e da una forte sorgente di luce UVA.
es - Proteger de la luz de sol directa y foco potente de luz UVA.
pt - Proteger da luz directa do sol e de fonte forte de luz UVA.
sv - Skyddas från direkt solljus och stark UVA-ljuskälla.
da - Beskyt mod direkte sollys og kraftig UVA- lys kilde.
fi - Suojattava suoranaiselta auringonvalolta ja voimakkaalta UVA –valolähteeltä".
no - Beskytt mot direkte sollys og sterk UVA lyskilde.
el - Προστατέψτε από την άμεση έκθεση στον ήλιο και σε πηγή φωτός δυνατής υπεριώδους ακτινοβολίας.
cs - Chraňte před přímým působením slunečního světla a silných zdrojů UVA záření.
ru - Предохранять от прямых солнечных лучей и источника насыщенного ультрафиолетового облучения.
pl - Chronić przed bezpośrednim promieniowaniem słonecznym i silnym źródłem promieniowania UVA.
tr - Doğrudan güneş ışığından ve güçlü UVA ışık kaynaklarından uzak tutulmalıdır.
sl - Zaščitite pred neposredno sončno svetlobo in močnim virom UVA svetlobe.
kk - Күн сәулесінің тура түсуінен және күшті УК сәулесінің көзінен қорғаңыз.
hr - Zaštititi od izravne sunčeve svjetlosti i jakog izvora UVA svjetla.
et - Kaitsta otsese päikesevalguse ja tugeva UVA-valguse allika eest.
lv - Aizsargājiet no tiešas saules gaismas un spēcīga ultravioletās A gaismas (UVA) avota iedarbības.
uk - Захищати від прямих сонячних променів та інтенсивного опромінення з джерела ультрафіолету типу А.
sk - Chráňte pred priamym slnečným svetlom a silným zdrojom UVA žiarenia.
sr - Čuvati van domašaja direktne sunčeve svetlosti i jakog UVA zračenja.

en - Non pyrogenic fluid path.
fr - Trajet apyrogène.
de - Pyrogenfreier Fließweg.
nl - Pyrogeenvrij vloeistoftraject.
it - Percorso del liquido apirogeno.
es - Paso de fluido apirógena.
pt - Passo de fluído não pirogénico.
sv - Pyrogenfri vätskeväg.
da - Non pyrogen væskebane.
fi - Pyrogeeniton nestetie.
no - Pyrogenfri væskebane.
el - Μη πυρετογόνος δίοδος υγρών.
cs - Apyrogenní dráha tekutiny.
ru - Апирогенная жидкость.
pl - Apirogenne obszary płynów.
tr - Apirojen sıvı yolu.
sl - Apirogena tekočinska pot. .
kk - Пирогендік емес сұйықтық ағатын жол
hr - Nepirogeni sustav za provođenje tekućine.
et - Mittepürogeenne vedelikutee.
lv - Apirogēna šķidruma plūsmas caurulīte.
uk - Апірогенна рідина.
sk - Nepyrogénne dráhy kvapalín.
sr - Kanal za nepirogenu tečnost


en - Sterile fluid path. Sterilized by a combination of steam and radiation.
fr - Trajet stérile. Stérilisé par une combinaison de vapeur et d'irradiation.
de - Steriler Fließweg. Sterilisiert durch eine Kombination aus Dampf und Bestrahlung.
nl - Steriel vloeistoftraject. Gesteriliseerd door een combinatie van stoom en bestraling.
it - Percorso del liquido sterile. Sterilizzato con sistema combinato di vapore ed irradiazione.
es - Paso de fluido estéril. Esterilizado por une combinación de vapor y radiación.
pt - Via estéril para fluidos. Esterilizado por uma combinação de vapor e radiações.
sv - Steril vätskeväg. Steriliserad genom en kombination av ånga och strålning.
da - Steril væsekbane. Steriliseret med en kombination af damp og stråling.
fi - Steriili nestetie. Steriloitu osittain höyryllä, osittain säteilyttämällä.
no - Steril væskebane. Sterilisert ved en kombinasjon av damp og stråling.
el - Στείρα δίοδος υγρών. Αποστειρωμένο με ένα συνδυασμό ατμού και ακτινοβολίας.
cs - Sterilní dráha tekutiny. Sterilizováno kombinací parní a radiační sterilizace.
ru - Стерильная жидкость. Стерилизовано паром и радиацией.
pl - Sterylne obszary płynów. Sterylizowane przez połączenie metod sterylizacji parą wodną i sterylizacji metodą napromieniowywania.
tr - Steril sıvı yolu. Buhar ve gamma radyasyon uygulaması kombinasyonu ile sterilize edilmiştir.
sl - Sterilna tekočinska pot. Sterilizirano s kombinacijo pare in sevanja.
kk - Зарарсыз сұйықтық ағатын жол. Буландыру мен сәулеленудің қосылуы арқылы зарасыздандырылған.
hr - Sterilni sustav za provođenje tekućine. Sterilizirano kombinacijom pare i zračenja.
et - Steriilne vedelikutee. Steriliseeritud üheaegselt auru ja kiirgusega.
lv - Sterila šķidruma plūsmas caurulīte. Sterilizēts, kombinēti izmantojot tvaiku un apstarošanu.
uk - Стерильна рідина. Стерилізовано комбінацією пари та радіації.
sk - Sterilné dráhy kvapalín. Sterilizované kombináciou pary a žiarenia.
sr - Sterilni kanal za tečnost. Sterilisan kombinovanjem pare i zračenja.


en - Do not resterilize
fr - Ne pas restériliser
de - Nicht resterilisieren
nl - Niet opnieuw steriliseren
it - Non risterilizzare
es - No lo reesterilice
pt - Não reesterilize
sv - Får inte omsteriliseras
da - Må ikke resteriliseres
fi - Ei saa steriloida uudelleen
no - Må ikke resteriliseres
el - Μην επαναποστειρώνετε
cs - Nesterilizujte
ru - Не стерилизуйте повторно
pl - Nie poddawać ponownej sterylizacji
tr - Tekrar sterilize etmeyin
sl - Ne sterilizirajte ponovno
kk - Қайта зарарсыздандырмаңыз
hr - Nemojte ponovno sterilizirati
et - Mitte uuesti steriliseerida
lv - Nesterilizēt atkārtoti
uk - Не стерилізуйте повторно
sk - Nesterilizujte opakovane
sr - Ne sterilisati ponovo

en - Apply label here.
fr - Placer toute étiquette ici.
de - Etikett hier anbringen.
nl - Label hier bevestigen.
it - Applicare qui l'etichetta.
es - Colocar etiqueta aquí.
pt - Aplicar o rótulo aqui.
sv - Fäst etikett här.
da - Påsæt etiket her.
fi - Kiinnitä etiketti tähän.
no - Fest etiketten her.
el - Τοποθετήστε την ετικέτα εδώ.
cs - Štítek umístěte zde.
ru - Место для маркировки.
pl - Zastosować odpowiednie oznakowanie.
tr - Etiketi buraya yapıştırınız.
sl - Oznako namestite tukaj.
kk - Осы жерге белгі қойыңыз.
hr - Ovdje pričvrstiti oznaku.
et - Kinnitage siia kleebis.
lv - Piestipriniet uzlīmi šeit.
uk - Місце для маркування.
sk - Sem nalepte štítok.
sr - Nalepnicu postavite ovde.

en - Do not vent.
fr - Ne pas utiliser de prise d'air.
de - Nicht belüften.
nl - Geen luchtinlaat gebruiken.
it - Non introdurre aria.
es - No ventilar.
pt - Não ventilar.
sv - Lufta ej.
da - Må ikke udluftes.
fi - Älä ilmasta.
no - Må ikke luftes.
el - Μη χρησιμοποιείτε αεραγωγό.
cs - Neodvzdušňujte.
ru - Не нарушать герметичность.
pl - Nie zapowietrzać.
tr - Hava ile temas ettirilmemelidir.
sl - Ne uporabljajte ventilacije.
kk - Теспеңіз.
hr - Ne prozračivati.
et - Mitte ventileerida.
lv - Nepakļaut ventilācijai.
uk - Не порушувати герметичність.
sk - Nevetrajte
sr - Ne ventilirati.

# INTERCEPT PROCESSING SET for PLASMA

**For use with INTERCEPT Illuminator**

Each set is wrapped in a tamper-evident package and includes one 15mL 6mM amotosalen hydrochloride solution container (Formula : Amotosalen HCl 203mg - Natr. chlorid. 924mg - Aqua ad iniect. ad 100mL), one illumination container, one compound adsorption device (CAD), three INTERCEPT Plasma storage containers. The set is sterilized by a combination of steam and radiation.

## Indications and Usage

Intended Use:

This set is used with an INTERCEPT Illuminator to inactivate a broad spectrum of viruses, bacteria, parasites as well as contaminating donor leukocytes in plasma.

Indications for Use:

INTERCEPT plasma is indicated for support of patients requiring plasma transfusions or therapeutic plasma exchange, according to clinical practice guidelines. Clinical trials in patients have demonstrated that plasma treated with the INTERCEPT Blood System was well tolerated and retained therapeutic efficacy comparable to conventional fresh frozen plasma.INTERCEPT Plasma may be used to treat single coagulation factor or antithrombotic protein deficiences for which no concentrates are available, as well as multiple coagulation factor and antithrombotic protein deficiencies. INTERCEPT Plasma may also be used for plasma exchange for thrombotic thrombocytopenic purpura (TTP). INTERCEPT treatment may be usedas an alternative to gamma irradiation for prevention of transfusion-associated graft-versus host disease (TA-GVHD). INTERCEPT treatment may be used in place of CMV testing and leukoreduction for prevention of transfusion-transmitted CMV infection.

INTERCEPT plasma may be stored from the time of collection for 12 months between -18°C and -25°C or for 24 months below -25°C, in compliance with applicable procedures and regulations.

Plasma photochemically treated with the INTERCEPT Bllod System may be stored and transfused according to standard methods for frozen plasma. Thawed INTERCEPT Plasma that has been stored at 2-6°C can be used up to 5 days. As with all plasma products, clinical use should consider that labile coagulation factors decline during post thaw storage

## Contraindications

Use of INTERCEPT Plasma is contraindicated in patients with a history of allergic response to amotosalen or psoralens.

## Precautions

Do not use if: tamper-evident package has been opened; signs of deterioration are visible; fluid path closures are loose or not intact; cannulae are broken or there is no fluid in amotosalen solution container.

Do not store above 25°C. Do not vent. Do not freeze. Protect the pack and tubing from sharp objects.

Unused sets in open aluminium foil may be kept 20 days at room temperature by folding and securing open end of aluminium foil. Units removed from the aluminium foil must be used within 24 hours.

Keep set in light-protective package until time of use. Protect from direct sunlight and strong UVA light source.

Set is single use only. Do not reuse. Do not resterilize. This product is not designed for reuse. Misuse can result in adverse reactions, including severe illness and possibly death.

All the following conditions must be met for pathogen inactivation:

- Plasma volume and red blood cell (RBC) content must be within the range specified in Table 1.
- Plasma mixed with amotosalen must be exposed to UVA light dose from INTERCEPT Illuminator. No other source of UVA light may be used.
- Plasma must be passed through the CAD by gravity flow process after illumination.
- For fresh plasma. the entire process from collection to freezing must be completed within a timeframe of 20 hours or according to local regulations.
- Fresh frozen plasma that has been thawed in accordance with local regulations must be immediately treated with the INTERCEPT Blood System for plasma and transfused or refrozen promptly after treatment.

This process is designed to be a closed system. Treatment with INTERCEPT Blood System does not replace applicable standards for processing in open and closed systems. If there is a leak in the set during processing, plasma product must be discarded.

Warnings : Amotosalen in contact with skin may result in photosensitisation in the presence of ultraviolet light. If skin exposure occurs, flush exposed skin copiously with water. Sterile connecting device (SCD) should be used according to manufacturer's instructions for use.

## Notes to Physicians

While laboratory studies of amotosalen processing with UVA light have shown a reduction in levels of certain viruses, bacteria and parasites; there is no pathogen inactivation process that has been shown to eliminate all pathogens.

INTERCEPT plasma components should not be prescribed to neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, and/or have a lower bound of the emission bandwidth <375 nm, due to the risk of erythema resulting from potential interaction between ultraviolet light (below 400 nm) and residual amotosalen.

## Instructions for Use

**Materials Needed:** One (1) INTERCEPT Processing Set for Plasma.

**Equipment Needed:** INTERCEPT Illuminator, Sterile Connecting Device (SCD), Tube Sealer.

Temperatures should be controlled to meet applicable regulations for plasma processing. Used and unused INTERCEPT sets should be discarded like any used blood containers, as biohazardous waste.

## Process Steps

**A-Plasma for Processing with the INTERCEPT Blood System**

Plasma products within the following ranges have been shown to be acceptable for use with this processing set.

**Table 1**

| Volume | RBC content |
|---|---|
| 385-650 mL | $<4 \times 10^6$ RBC/mL |

**B- Amotosalen Addition**

1. Remove set from package.
2. Weld tubing from plasma container to amotosalen container tubing using SCD.
3. Disassemble set from organizer and remove rubber band.
4. If two plasma units will be produced by the INTERCEPT process, heat seal and remove one storage container.
5. Label set containers using appropriate donation identification. See warning in section C. While labeling storage containers, separate them to ensure they do not adhere to one another.
6. Hang plasma container. ensuring that set containers/components do not come in contact with floor. Break both cannulae on amotosalen container.
7. Allow plasma and amotosalen solution to flow into illumination container marked by number "1".
8. Ensure that plasma drains completely from initial plasma container into illumination container.
9. Express air from the illumination container into the amotosalen container.
10. When air is removed and plasma has fully drained back into the illumination container, mix illumination container thoroughly by gentle agitation to ensure complete mixing of amotosalen and plasma.
11. Express a small amount of plasma and amotosalen mixture into tubing, filling at least 4cm of tubing.
12. Seal tubing between illumination container and amotosalen container within the 4cm. Warning : During illumination, tubing must be held within large compartment of illumination tray.
13. Remove and discard initial plasma container, amotosalen container and excess tubing.

**C- Illumination**

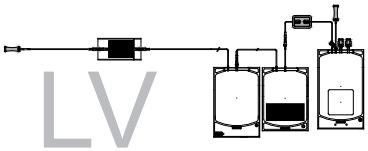
Illuminate plasma.

Refer to INTERCEPT Illuminator Operator's Manual for complete illumination instructions for use. Warning : All plasma, both in illumination container and tubing, must be within large compartment of illuminator tray in order for inactivation to occur. The process requires unimpeded light transmission through tray and illumination container with plasma. No labels or other material should be on this area. Tray must be clean. Labels should be placed on illumination container flap only. Illumination container should lay flat.

**D- Processing with Compound Adsorption Device (CAD)**

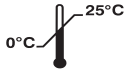
1. Hang illumination container, allowing CAD to hang freely, with storage containers kept in an inverted position.
2. Close clamp on bypass line; ensure all other clamps are open.
3. Break cannula on illumination container and allow plasma to flow through CAD marked with the number "2" into storage containers marked with the number "3".
4. Once plasma has emptied from illumination container and passed through CAD, close clamp on tubing leading from the CAD and open clamp on the bypass line.
5. Hang CAD together with illumination container.
6. Remove storage containers from tab on CAD and allow them to hang ports up.
7. Completely express air from storage containers through bypass line.
8. Close clamp on the bypass line and open the clamps on storage containers.
9. Open clamp below the CAD, allowing plasma to drain into storage containers.
10. Ensure that the storage container tubing contains plasma and no air. Close clamps on storage containers.
11. Re-distribute plasma volume between storage containers, if necessary.
12. Ensure appropriate donor identification is attached to each filled plasma storage container.
13. Disconnect storage containers from set by heat-sealing, allowing sufficient tubing length for segments.
14. Discard CAD and illumination container. The INTERCEPT Plasma process is now complete.
15. Seal tubing as appropriate for making segments as needed.
16. Follow internal procedures for freezing plasma.

INTERCEPT BLOOD SYSTEM



# LV

en - Do not use if the product, its sterile barrier system or its packaging is damaged or shows any sign of deterioration.
fr - Ne pas utiliser si le produit, sa barrière de stérilité ou son emballage a été endommagé ou s'il présente des signes d'altération.
de - Nicht verwenden, wenn das Produkt, die Sterilverpackung oder dessen Umverpackung beschädigt ist oder Anzeichen von Verfall zeigt.
nl - Niet gebruiken indien het product, de steriele barrière of de verpakking beschadigd is of tekenen van beschadiging vertoont.
it - Non utilizzare se il prodotto, la sua barriera sterile o il suo confezionamento sono danneggiati o mostrano segni di deterioramento.
es - No usar si el producto, su barrera estéril o su envase está dañado o muestra cualquier signo de deterioro.
pt - Não utilizar caso ou produto, a sua proteção estéril ou a sua embalagem estejam danificados ou apresentem quaisquer sinais de deterioração.
sv - Används ej om produkten, dess sterilbarriär eller dess förpackning är skadad eller visar några tecken på avvikelse.
da - Må ikke anvendes hvis produktet, sterilbarriererne eller pakningerne er beskadigede eller der er tegn på brud.
fi - Älä käytä jos tuotteen steriilisuojat ovat irti tai pakkaus on silminnähden vahingoittunut.
no - Må ikke brukes dersom pruduktet, dets sterilbarriere eller emballasje er skadet eller viser tegn til forringelse.
el - Μη χρησιμοποιείτε, εάν το προϊόν, το στείρο σύστημα φραγμού του ή η συσκευασία του είναι κατεστραμμένα ή παρουσιάζει οποιοδήποτε σημάδι φθοράς.
cs - Nepoužívejte , jestliže je výrobek, jeho sterilní barierový systém nebo obal poškozen, nebo vykazuje-li jakékoli známky porušení.
ru - Не использовать, если нарушена целостность продукта, системы стерильной преграды, упаковки или при наличии видимых признаков повреждения.
pl - Nie używać jeżeli produkt, jego system bariery sterylnej lub jego opakowanie jest zniszczone lub wykazuje jakiekolwiek oznaki uszkodzenia.
tr - Ürün, steril bariyer sistemi veya ambalaj zarar görmüşse ya da bozulme belirtisi varsa kullanmayınız.
sl - Ne uporabite, če so izdelek, sterilni zaščitni sistem ali ovojnina poškodovani ali kažejo znake poslabšanja kakovosti.
kk - Зарарсыздандыруды қорғау жүйесінің немесе қаптамасының зақымданғаның немесе нашарлауының белгілерін көрсеңіз, өнімді қолданбаңыз.
hr - Ne upotrebljavati ako su proizvod, sterilni zaštitni sustav ili ambalaža oštećeni ili ako pokazuju bilo kakav znak pogoršanja kakvoće.
et - Ärge kasutage, kui toode, selle steriilne barjäärisüsteem või pakend on vigastatud või nähtavate riknemismärkidega.
lv - Nelietojiet izstrādājumu, ja izstrādājums, tā sterilā barjersistēma vai iepakojums ir bojāts, vai ir redzamas jebkādas bojājuma pazīmes.
uk - Не використовувати, якщо порушено цілісність продукту, його системи стерильної перепони чи упаковки, або є будь-яка ознака наявного пошкодження.
sk - Nepoužívajte, ak je výrobok, jeho sterilná bariéra alebo jeho obal poškodený alebo vykazuje známky porušenia.
sr - Ne koristiti ako su proizvod, sistem sterilne barijere ili pakovanje oštećeni ili na njima postoje bilo kakvi znaci propadanja.




en - Do not freeze. Do not store above 25°C.
fr - Ne pas congeler. Ne pas stocker à plus de 25°C.
de - Nicht einfrieren. Nicht über 25°C lagern.
nl - Niet invriezen. Niet bewaren boven 25°C.
it - Non congelare. Non conservare a temperature superiori a 25°C.
es - No congelar. No almacenar por encima de 25°C.
pt - Não congelar. Não guardar acima de 25°C.
sv - Får ej frysa. Förvaras ej över 25°C.
da - Må ikke fryses. Må ikke opbevares over 25°C.
fi - Ei saa jäätyä. Älä säilytä yli 25°C.
no - Må ikke fryses. Må ikke lagres i temperatur over 25°C.
el - Μην καταψύχετε. Μην αποθηκεύετε σε θερμοκρασία άνω των 25°C.
cs - Nezmrazujte. Neskladujte nad 25°C.
ru - Не замораживать. Не хранить при температуре выше 25°C.
pl - Nie zamrażać. Nie przechowywać w temperaturze powyżej 25°C.
tr - Dondurmayın. 25 C'nin üzerinde saklamayınız.
sl - Ne zamrznite. Ne hranite pri temperaturi nad 25°C.
kk - Тоңазытпаңыз. 25°C-тан жоғары температурада сақтамаңыз.
hr - Ne smrzavati. Čuvati na temperaturi ispod 25 °C.
et - Mitte hoida sügavkülmas. Mitte hoida temperatuuril üle 25 °C.
lv - Nesasaldēt. Uzglabāt līdz 25°C temperatūrā.
uk - Не заморожувати. Не зберігати при температурі вище 25 °C.
sk - Nezmrazujte. Neskladujte pri teplote nad 25 °C.
sr - Ne zamrzavati. Ne čuvati na temperaturama iznad 25°C.

**LV**

en - Large Volume
fr - Grand volume
de - Großvolumen
nl - Groot volume
it - Grande volume
es - Volumen grande
pt - Grande volume
sv - Stor volym
da - Stor volumen
fi - Suuri tilavuus
no - tort volum
el - Μεγάλης χωρητικότητας
cs - Velký objem
ru - Большой объем
pl - Duża objętość
tr - Büyük Hacim
sl - Velika prostornina
kk - Үлкен көлемдік
hr - Veliki volumen
et - Suur maht
lv - Liels tilpums
uk - Великий об'єм
sk - Veľký objem
sr - Veliki volumen

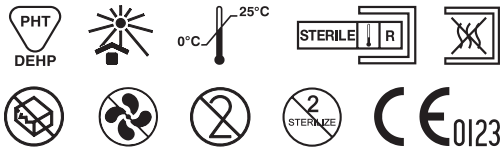
en - Platelet Storage Container
fr - Poche de conservation du concentré plaquettaire
de - Thrombozyten-Lagerungsbeutel
nl - Trombocytenbewaarzak
it - Sacca per la conservazione delle piastrine
es - Bolsa de almacenamiento de plaquetas
pt - Recipiente de conservação de plaquetas
sv - Förvaringspåse för trombocyter
da - Trombocytopbevaringspose
fi - Trombosyyttien säilytyspussi
no - Lagringspose for blodplater
el - περιέκτης αποθήκευσης αιμοπεταλίων
cs - Zásobník na skladování trombocytů
ru - Контейнер для хранения тромбоцитов
pl - Pojemnik do przechowywania preparatu płytek krwi
tr - Trombosit Saklama Kabı
sl - Vsebnik za shranjevanje trombocitov
kk - Тромбоцит сақтау ыдысы
hr - Spremnik za pohranu trombocita
et - Trombotsüütide säilituskott
lv - Trombocītu glabāšanas konteiners
uk - Контейнер для зберігання тромбоцитів
sk - Zásobník na skladovanie trombocytov
sr - Posuda za čuvanje trombocita

en - Refer to Instructions for Use
fr - Consulter la notice
de - Siehe Gebrauchsanleitung
nl - Raadpleeg de gebruiksaanwijzing
it - Consultare le istruzioni per l'uso
es - Consulte las instrucciones de uso
pt - Consultar as instruções de utilização
sv - Se bruksanvisningen
da - Se brugsanvisningen
fi - Katso käyttöhjeet
no - Se bruksanvisningen
el - Συμβουλευτείτε τις οδηγίες χρήσης
cs - Viz návod k použití
ru - См. инструкцию по применению
pl - Proszę zapoznać się z instrukcją użytkowania
tr - Kullanma talimatına başvurun
sl - Pozor: Glejte navodilo za uporabo!
kk - Пайдалану нұсқаулықтарын қараңыз
hr - Vidi upute za uporabu
et - Tutvuge kasutusjuhendiga
lv - Skatiet lietošanas instrukciju
uk - Звертайтесь до вказівок із використання
sk - Prečítajte si návod na použitie
sr - Pogledajte uputstvo za upotrebu


**Cerus Corporation**
2550 Stanwell Drive
Concord, CA 94520 USA

EC REP

**Cerus Europe B.V.**
Stationsstraat 79-D
3811 MH Amersfoort
The Netherlands



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INTERCEPT BLOOD SYSTEM

en - Protect from direct sunlight and strong UVA light source.
fr - Protéger des rayons directs du soleil et d'une source puissante de rayons U.V.A.
de - Vor direkter Sonneneinstrahlung und starker UVA-Strahlung schützen.
nl - Beschermen tegen direct zonlicht en krachtige bronnen van uva-licht.
it - Proteggere dalla luce solare diretta e da una forte sorgente di luce UVA.
es - Proteger de la luz de sol directa y foco potente de luz UVA.
pt - Proteger da luz directa do sol e de fonte forte de luz UVA.
sv - Skyddas från direkt solljus och stark UVA-ljuskälla.
da - Beskyt mod direkte sollys og kraftig UVA- lys kilde.
fi - Suojattava suoranaiselta auringonvalolta ja voimakkaalta UVA – valolähteeltä".
no - Beskytt mot direkte sollys og sterk UVA lyskilde.
el - Προστατέψτε από την άμεση έκθεση στον ήλιο και σε πηγή φωτός δυνατής υπεριώδους ακτινοβολίας.
cs - Chraňte před přímým působením slunečního světla a silných zdrojů UVA záření.
ru - Предохранять от прямых солнечных лучей и источника насыщенного ультрафиолетового облучения.
pl - Chronić przed bezpośrednim promieniowaniem słonecznym i silnym źródłem promieniowania UVA.
tr - Doğrudan güneş ışığından ve güçlü UVA ışık kaynaklarından uzak tutulmalıdır.
sl - Zaščitite pred neposredno sončno svetlobo in močnim virom UVA svetlobe.
kk - Күн сәулесінің тура түсуінен және күшті УК сәулесінің көзінен қорғаңыз.
hr - Zaštititi od izravne sunčeve svjetlosti i jakog izvora UVA svjetla.
et - Kaitsta otsese päikesevalguse ja tugeva UVA-valguse allika eest.
lv - Aizsargājiet no tiešas saules gaismas un spēcīga ultravioletās A gaismas (UVA) avota iedarbības.
uk - Захищати від прямих сонячних променів та інтенсивного опромінення з джерела ультрафіолету типу А.
sk - Chráňte pred priamym slnečným svetlom a silným zdrojom UVA žiarenia.
sr - Čuvati van domašaja direktne sunčeve svetlosti i jakog UVA zračenja.

PHT
DEHP

en - Contains or presence of phthalates: Di-(2-ethylhexyl)phthalate (DEHP).
fr - Trace ou présence de phtalates : phtalate de di(2-éthylhexyle) (DEHP)
de - Phthalate sind enthalten oder vorhanden: Di-(2-ethylhexyl)phthalat (DEHP).
nl - Bevat ftalaten: Di-(2-ethylhexyl)ftalaat (DEHP).
it - Contiene ftalati o presenta tracce di ftalati: di-(2-etilesil)ftalato (DEHP).
es - Contiene o puede que haya ftalatos presentes: Di(2-etilhexil) ftalato (DEHP).
pt - Contém ou existe a presença de ftalatos: Dietilhexilftalato (DEHP).
sv - Innehåller ftalater/förekomst av ftalater: Di-(2-etylhexyl)ftalat (DEHP).
da - Indeholder eller tilstedeværelse af phthalater: Di-(2-ethylhexyl)phthalat (DEHP).
fi - Sisältää ftalaatteja: di(2-etyyliheksyyli)ftalaatti (DEHP).
no - Innehold, eller tilstedeværelse av, ftalater: Di-(2-etylheksyl)ftalat (DEHP).
el - Περιέχει φθαλικά ή ίχνη φθαλικών: Φθαλικός δι(2-αιθυλεξυλ) εστέρας (DEHP).
cs - Obsah nebo přítomnost ftalátů: Di-(2-ethylhexyl)ftalát (DEHP).
ru - Содержание или наличие фталатов: ди-(2-этилгексил)фталат (диоктилфталат, ДОФ).
pl - Zawartość lub obecność ftalanów: Ftalan di-(2-etyloheksylu) (DEHP).
tr - Ftalatlar içerir veya vardır: Di-(2-etilheksil)ftalat (DEHP).
sl - Vsebnost ali prisotnost ftalatov: di-(2-etilheksil)ftalat (DEHP).
kk - Фталаттардың мөлшері немесе бар болуы: Ди-(2-этилгексил) фталат (ДЭГФ)
hr - Sadržaj ili prisutnost ftalata: di-(2-etilheksil) ftalat (DEHP).
et - Sisaldab ftalaate: di-(2-etüülheksüül)ftalaat (DEHP).
lv - Satur ftalātus: di-(2-etilheksil)ftalāts (DEHP).
uk - Вміст або наявність фталатів: ді-(2-етилгексил)фталат (діоктилфталат, ДОФ)
sk - Obsah alebo prítomnosť ftalátov: Di-(2-etylhexyl)ftalát (DEHP).
sr - Sadrži ili su prisutni ftalati: di-(2-etilheksil)ftalat (DEHP).

STERILE R

en - Sterile fluid path. Sterilized by a combination of steam and radiation.
fr - Trajet stérile. Stérilisé par une combinaison de vapeur et d'irradiation.
de - Steriler Fließweg. Sterilisiert durch eine Kombination aus Dampf und Bestrahlung.
nl - Steriel vloeistoftraject. Gesteriliseerd door een combinatie van stoom en bestraling.
it - Percorso del liquido sterile. Sterilizzato con sistema combinato di vapore ed irradiazione.
es - Paso de fluido estéril. Esterilizado por une combinación de vapor y radiación.
pt - Via estéril para fluidos. Esterilizado por uma combinação de vapor e radiações.
sv - Steril vätskeväg. Steriliserad genom en kombination av ånga och strålning.
da - Steril væsekbane. Steriliseret med en kombination af damp og stråling.
fi - Sterili nestetie. Steriloitu osittain höyryllä, osittain säteilyttämällä.
no - Steril væskebane. Sterilisert ved en kombinasjon av damp og stråling.
el - Στείρα δίοδος υγρών. Αποστειρωμένο με ένα συνδυασμό ατμού και ακτινοβολίας.
cs - Sterilní dráha tekutiny. Sterilizováno kombinací parní a radiační sterilizace.
ru - Стерильная жидкость. Стерилизовано паром и радиацией.
pl - Sterylne obszary płynów. Sterylizowane przez połączenie metod sterylizacji parą wodną i sterylizacji metodą napromieniowywania.
tr - Steril sıvı yolu. Buhar ve gamma radyasyon uygulaması kombinasyonu ile sterilize edilmiştir.
sl - Sterilna tekočinska pot. Sterilizirano s kombinacijo pare in sevanja.
kk - Зарарсыз сұйықтық ағатын жол. Буландыру мен сәулеленудің қосылуы арқылы зарасыздандырылған.
hr - Sterilni sustav za provođenje tekućine. Sterilizirano kombinacijom pare i zračenja.
et - Steriilne vedelikutee. Steriliseeritud üheaegselt auru ja kiirgusega.
lv - Sterila šķidruma plūsmas caurulīte. Sterilizēts, kombinēti izmantojot tvaiku un apstarošanu.
uk - Стерильна рідина. Стерилізовано комбінацією пари та радіації.
sk - Sterilné dráhy kvapalín. Sterilizované kombináciou pary a žiarenia.
sr - Sterilni kanal za tečnost. Sterilisan kombinovanjem pare i zračenja.

en - Non pyrogenic fluid path.
fr - Trajet apyrogène.
de - Pyrogenfreier Fließweg.
nl - Pyrogeenvrij vloeistoftraject.
it - Percorso del liquido apirogeno.
es - Paso de fluido apirógena.
pt - Passo de fluído não pirogénico.
sv - Pyrogenfri vätskeväg.
da - Non pyrogen væskebane.
fi - Pyrogeeniton nestetie.
no - Pyrogenfri væskebane.
el - Μη πυρετογόνος δίοδος υγρών.
cs - Apyrogenní dráha tekutiny.
ru - Апирогенная жидкость.
pl - Apirogenne obszary płynów.
tr - Apirojen sıvı yolu.
sl - Apirogena tekočinska pot. .
kk - Пирогендік емес сұйықтық ағатын жол
hr - Nepirogeni sustav za provođenje tekućine.
et - Mittepürogeenne vedelikutee.
lv - Apirogēna šķidruma plūsmas caurulīte.
uk - Апірогенна рідина.
sk - Nepyrogénne dráhy kvapalín.
sr - Kanal za nepirogenu tečnost

en - Apply label here.
fr - Placer toute étiquette ici.
de - Etikett hier anbringen.
nl - Label hier bevestigen.
it - Applicare qui l'etichetta.
es - Colocar etiqueta aquí.
pt - Aplicar o rótulo aqui.
sv - Fäst etikett här.
da - Påsæt etiket her.
fi - Kiinnitä etiketti tähän.
no - Fest etiketten her.
el - Τοποθετήστε την ετικέτα εδώ.
cs - Štítek umístěte zde.
ru - Место для маркировки.
pl - Zastosować odpowiednie oznakowanie.
tr - Etiketi buraya yapıştırınız.
sl - Oznako namestite tukaj.
kk - Осы жерге белгі қойыңыз.
hr - Ovdje pričvrstiti oznaku.
et - Kinnitage siia kleebis.
lv - Piestipriniet uzlīmi šeit.
uk - Місце для маркування.
sk - Sem nalepte štítok.
sr - Nalepnicu postavite ovde.

en - Do not vent.
fr - Ne pas utiliser de prise d'air.
de - Nicht belüften.
nl - Geen luchtinlaat gebruiken.
it - Non introdurre aria.
es - No ventilar.
pt - Não ventilar.
sv - Lufta ej.
da - Må ikke udluftes.
fi - Älä ilmasta.
no - Må ikke luftes.
el - Μη χρησιμοποιείτε αεραγωγό.
cs - Neodvzdušňujte.
ru - Не нарушать герметичность.
pl - Nie zapowietrzać.
tr - Hava ile temas ettirilmemelidir.
sl - Ne uporabljajte ventilacije.
kk - Теспеңіз.
hr - Ne prozračivati.
et - Mitte ventileerida.
lv - Nepakļaut ventilācijai.
uk - Не порушувати герметичність.
sk - Nevetrajte
sr - Ne ventilirati.

2 STERILIZE

en - Do not resterilize
fr - Ne pas restériliser
de - Nicht resterilisieren
nl - Niet opnieuw steriliseren
it - Non risterilizzare
es - No lo reesterilice
pt - Não reesterilize
sv - Får inte omsteriliseras
da - Må ikke resteriliseres
fi - Ei saa steriloida uudelleen
no - Må ikke resteriliseres
el - Μην επαναποστειρώνετε
cs - Nesterilizujte
ru - Не стерилизуйте повторно
pl - Nie poddawać ponownej sterylizacji
tr - Tekrar sterilize etmeyin
sl - Ne sterilizirajte ponovno
kk - Қайта зарарсыздандырмаңыз
hr - Nemojte ponovno sterilizirati
et - Mitte uuesti steriliseerida
lv - Nesterilizēt atkārtoti
uk - Не стерилізуйте повторно
sk - Nesterilizujte opakovane
sr - Ne sterilisati ponovo

INTERCEPT BLOOD SYSTEM

# INTERCEPT PROCESSING SET for LARGE VOLUME PLATELET UNITS

**For use with INTERCEPT Illuminator**

Each set is wrapped in a tamper-evident package and includes one 17.5mL 3mM amotosalen hydrochloride solution container (Formula : Amotosalen HCl 101mg - Natr. chlorid. 924mg - Aqua ad iniect. ad 100mL), one illumination container, one container with Compound Adsorption Device (CAD), one INTERCEPT platelet storage container. The set is sterilized by a combination of steam and radiation.

## Indications and Usage

This set is used with an INTERCEPT Illuminator to inactivate a broad spectrum of viruses, bacteria and parasites as well as contaminating donor leukocytes in platelet components. INTERCEPT platelets are indicated for support of patients requiring platelet transfusions, according to clinical practice guidelines. INTERCEPT platelets suspended in additive solution or in 100% plasma may be stored up to 7 days from time of collection. Treated platelets must be stored at 20-24°C with continuous agitation. Any extension of platelet storage time from current blood center limits should be evaluated per Directive [2004/33/EC] and validated according to local blood bank procedures.

Platelet additive solutions approved for use with INTERCEPT: InterSol, SSP+, T-PAS+, Grifols PAS III M.

## Contraindications

Use of INTERCEPT platelets is contraindicated in patients with a history of allergic response to amotosalen or psoralens.

## Precautions

Do not use if : tamper-evident package has been opened; signs of deterioration are visible; fluid path closures are loose or not intact; cannulae are broken or there is no fluid in amotosalen solution container.

Do not store above 25°C. Do not vent. Do not freeze. Protect the pack and tubing from sharp objects.

Unused sets in open aluminium foil may be kept 20 days at room temperature by folding and securing open end of aluminium foil. Units removed from the aluminium foil must be used within 8 hours.

Keep set in light-protective package until time of use. Protect from direct sunlight and strong UVA light source.

Set is single use only. Do not reuse. Do not resterilize. This product is not designed for reuse. Misuse can result in adverse reactions, including severe illness and possibly death.

All the following conditions must be met for pathogen inactivation:

- Platelets must be prepared in the volume range specified in **Table 1** based on the suspension medium used by the blood center.
- Platelet count, volume and red blood cell (RBC) content must be within ranges specified in**Table1.**
- Platelets mixed with amotosalen must be exposed to UVA light dose from INTERCEPT Illuminator. No other source of UVA light may be used.
- Platelets collected on Day 0 must be exposed to UVA light by end of Day 1.
- After illumination, platelets must be agitated in CAD container in accordance with the durations specified in **Table 2**; duration is dependent on the suspension medium.

This process is designed to be a closed system. Treatment with INTERCEPT Blood System does not replace applicable standards for processing in open and closed systems. If there is a leak in the set during processing, platelet product must be discarded.

Warnings : Amotosalen in contact with skin may result in photosensitisation in the presence of ultraviolet light. If skin exposure occurs, flush exposed skin copiously with water. Sterile connecting device (SCD) should be used according to manufacturer's instructions for use.

## Notes to Physicians

While laboratory studies of amotosalen processing with UVA light have shown a reduction in levels of certain viruses and bacteria, there is no pathogen inactivation process that has been shown to eliminate all pathogens.

Neonatal patients who require platelet transfusion during phototherapy for treatment of hyperbilirubinemia should not be treated with phototherapy devices that emit light less than 425nm to avoid the theoretical potentiation of erythema resulting from interaction between UVA light and psoralen.

## Instructions for Use

**Materials Needed** : One (1) INTERCEPT Processing Set for Large Volume Platelet Units.

**Equipment Needed** : INTERCEPT Illuminator, Sterile Connecting Device (SCD), Tube Sealer, Flatbed Agitator.

Temperatures should be controlled to meet applicable regulations for platelet processing.

Used and unused INTERCEPT sets should be discarded like any used blood containers, as biohazardous waste.

## Process Steps

### A- Preparation of Platelets

Platelets can be prepared in additive solution or in 100% plasma **(Table 1)**. Platelet products within the following ranges have been shown to be acceptable for use with this processing set.

**Table 1**

| Suspension Medium | | Platelet Count | Volume | RBC Content |
|---|---|---|---|---|
| Plasma Content | Additive Solution Content | | | |
| 32 - 47% | 53 - 68% | 2.5 - 7.0 x $10^{11}$ | 300 - 420 mL | <4 x $10^{6}$ RBC/mL |
| 100% | 0% | 2.5 - 7.0 x $10^{11}$ | 255 - 420 mL | <4 x $10^{6}$ RBC/mL |

### B- Amotosalen Addition to Platelets

1. Remove set from package. Unwrap only illumination container from organizer.
2. Weld tubing from platelet container to amotosalen container tubing using SCD.
3. Label set containers using appropriate donation identification. See warning in Section C.
4. Hang platelets and break both cannulae on amotosalen container.
5. Allow platelets and amotosalen solution to flow into illumination container, marked by number "1".
6. Ensure that platelets are completely transferred to illumination container by expressing air from platelet and amotosalen container into illumination container.
7. When platelets are in illumination container, mix thoroughly by gentle agitation to ensure complete mixing of amotosalen and platelets.
8. Express air from platelets into amotosalen container.
9. Express a small amount of platelet and amotosalen mixture into tubing, filling about 4cm of tubing.
10. Seal tubing between illumination container and amotosalen container, so that tubing is no longer than approximately 4cm from illumination container inlet port.
    Warning : During illumination, tubing must be held within large compartment of illumination tray.
11. Remove and discard empty platelet and amotosalen containers.

### C- Illumination

Illuminate platelets.

Refer to INTERCEPT Illuminator Operator's Manual for complete illumination instructions for use.

Warning : Platelets in illumination container must be within large compartment of illuminator tray in order for inactivation to occur. The process requires unimpeded light transmission through tray and illumination container with platelets. No labels or other material should be on this area. Tray must be clean. Labels should be placed on illumination container flap only. Illumination container should lay flat.

### D- Agitation with CAD

Warning : Do not fold or bend CAD.

1. Unwrap set from organizer.
2. Hang platelets, break cannula and allow platelets to flow into CAD container, marked by number "2".
3. Express air from CAD container into illumination container.
4. Seal tubing close to inlet port of CAD container.
5. Remove and discard empty illumination container.
6. Place CAD container on flatbed agitator for the duration specified in **Table 2** based on the suspension medium.

**Table 2**

| Suspension Medium | CAD Agitation Duration |
|---|---|
| Additive Solution (53 - 68%) | 6 to 16 hours |
| Plasma (100%) | 16 to 24 hours |

### E- Transfer to Storage Container

1. Remove platelets from agitator and hang platelets.
2. Close clamp on platelet sampling pouch.
3. Break cannula and allow platelets to flow into storage container, marked by number "3".
4. Express air from storage container into CAD container.
5. Seal tubing close to inlet port of storage container.
6. Remove and discard empty CAD container. Place platelets on platelet agitator.

The INTERCEPT Platelet process is now complete.

### F- Sampling Platelet Product (optional)

1. Mix INTERCEPT platelets by gently agitating platelet storage container.
2. Open clamp to platelet sampling pouch and squeeze several times.
3. Allow sampling pouch to fill with platelets. Seal tubing.
4. Remove sample pouch.
5. Transfer sample to appropriate laboratory tube immediately.

**Caution**: DEHP is known to be released from polyvinyl chloride (PVC) medical devices; increased leaching can occur with extended storage or increased surface area contact. The INTERCEPT processing sets only have tubing components, container ports and, if included, an in-line filter that contain PVC; all containers and other parts are PVC-free. During use of this processing set, blood components are in contact with PVC for a brief period of time (approx. <15 minutes). Based on limited surface area contact and minimal contact time, DEHP levels in blood components after use of the processing set are estimated to be well below those resulting from other medical applications containing PVC tubing (e.g. hemodialysis, intravenous fluid administration, extracorporeal membrane oxygenation and cardiopulmonary bypass procedures). The risks associated with DEHP released to the blood components must be weighed against the benefits of therapeutic transfusion and inactivation of harmful viruses, bacteria and other pathogens.