* 1 0 5 7 *

REF BEPC4129

Baxter

Locking Titanium PD Catheter Adapter

3 pozicija

eng

Description

This adapter is a double sealing female Luer lock adapter with a 2-piece, combination compression fit/barbed catheter connector. The adapter is used to connect the PD catheter to a solution transfer set with locking connector. This adapter is compatible with peritoneal dialysis catheters of nominal measurements of 2.6mm ID / 5mm OD and 3.5mm ID / 5.1mm OD.

Sterile nonpyrogenic, Sterilized using ethylene oxide.

Indications for use: The Locking Titanium Adapter for Peritoneal Dialysis Catheter is intended to secure the peritoneal catheter tubing to the Baxter transfer set used during Peritoneal Dialysis therapy.

Contraindications

Do not use povidone-iodine to connect the Transfer Set to the Baxter Titanium Adapter if there is a known history of allergic reaction to iodine. Use other disinfectants or antiseptic agents that do not contain iodine, hydrogen peroxide, alcohol, or bleach.

Warnings

Use aseptic technique. Contamination of any portion of the fluid path may result in peritonitis.

This device is intended for one time connection to the patient's peritoneal dialysis catheter. Do not reuse this device. Reuse or reprocessing of this device may lead to contamination and compromised device function or structural integrity.

It is recommended that thyroid function be monitored in patients with small peritoneal dialysate fill volumes, typically infants and children. In order to minimize iodine exposure, drain the contents of the peritoneal cavity to the drain receptacle prior to initiation of next fill cycle whenever clinically possible.

Do not use if pouch is damaged.

Contamination at the time of adapter insertion may result in peritonitis. The adapter should be inserted into a sterile catheter following the procedure below.

Many dialysis products available from other manufacturers are used with equipment or disposables from Baxter Healthcare Corporation. Baxter has no control over variability, tolerances, mechanical strength or changes in these products which may be made from time to time. Therefore, Baxter cannot ensure that the dialysis products of other manufacturers, when connected with its products, will function in a satisfactory manner.

Directions for Use

Use aseptic technique

1. Create an aseptic field. Place the adapter onto the aseptic field.
2. For general procedure on preparation of catheter, refer to catheter instructions for use when applicable.
3. Clamp the catheter.
4. Scrub the connection with povidone-iodine using sterile gauze for 1 minute.
5. Soak the catheter adapter and the catheter tubing in povidone-iodine solution for 5 minutes.
6. When applicable remove the used adapter by cutting the catheter with sterile scissors immediately below the adapter. Cut the catheter to provide straight edges to facilitate seating.
7. Insert the small non-threaded end of the locking adapter sleeve onto the catheter. Slide the sleeve up the catheter to expose the end of the catheter.
8. Insert the catheter adapter into the catheter up to the shoulder. After insertion, inspect the catheter tubing at the insertion site to verify that the adapter is completely seated, and that there are no splits or tears in the catheter. The adapter should fit snugly into the catheter, pulling on the adapter should cause no slippage with the catheter.
9. Slide the sleeve back down the catheter toward the adapter. Screw the sleeve onto the adapter until firmly seated.
10. Soak the catheter with adapter in povidone-iodine solution an additional 5 minutes.
11. Cap the adapter with Locking Cap for Peritoneal Dialysis Catheter Adapter or attach the Transfer Set.
12. Remove the catheter clamp.
13. Discard the used adapter per local waste disposal guidelines.

Do not re-use

Consult instructions for use

Non-pyrogenic

Do not use if package is damaged.

RT Store at room temperature

Manufacturer

STERILE EO Sterilized using ethylene oxide

Titan-Adapter mit Überwurfmutter

ger

Beschreibung

Dieser Adapter hat einen weiblichen Luer-Anschluss mit doppelter Dichtung und besteht aus einer Überwurfmutter und einer Stecknippelverbindung. Der Adapter wird verwendet, um den PD-Katheter an ein Überleitungssystem mit Schraubkonnektor anzuschließen. Dieser Adapter ist kompatibel mit Peritonealdialysekathetern mit den Nennabmessungen 2,6 mm ID/5 mm AD und 3,5 mm ID/5,1 mm AD.

Steril und pyrogenfrei. Sterilisiert mit Ethylenoxid.

Anwendungsgebiete: Der Titan-Adapter mit Überwurfmutter für Peritonealdialysekatheter ist dafür bestimmt, den Schlauch des Peritonealkatheters mit dem während der Dialyse verwendeten Baxter-Überleitungsset zu verbinden.

Gegenanzeigen

Bei der Verbindung des Überleitungssets mit dem Baxter Titan-Adapter kein Povidon-Jod verwenden, wenn beim Patienten eine bekannte allergische Reaktion gegen Jod vorliegt. Verwenden Sie andere Desinfektionsmittel oder Antiseptika, die weder Jod noch Wasserstoffperoxid, Alkohol oder Chlorbleiche enthalten.

Warnhinweise

Achten Sie auf aseptische Arbeitsweise. Wenn Teile des Fließwegs kontaminiert sind, besteht die Gefahr einer Peritonitis.

Dieses Produkt ist bestimmt für den einmaligen Gebrauch beim Anschluss des Peritonealdialysekatheters des Patienten. Nicht wiederverwenden. Die Wiederverwendung oder Wiederaufbereitung dieses Produkts kann zu Kontamination führen und die Funktion und strukturelle Integrität des Produkts beeinträchtigen.

Bei Patienten mit geringen Peritonealdialysat-Füllvolumina, in der Regel Kleinkindern und Kindern, wird eine Überwachung der Schilddrüsenfunktion empfohlen. Um die Jod-Exposition zu minimieren, lassen Sie vor Beginn des nächsten Füllzyklus den Inhalt der Peritonealhöhle in den Auffangbeutel ablaufen, sofern dies klinisch möglich ist.

Nicht verwenden, wenn der Verpackungsbeutel beschädigt ist.

Bei einer Kontamination bei Adaptereinführung besteht die Gefahr einer Peritonitis. Der Adapter ist in einen sterilen Katheter einzuführen, dabei ist der nachstehend beschriebene Ablauf zu befolgen.

Eine Reihe von Dialyseprodukten anderer Hersteller wird mit Geräten oder Einmalprodukten der Baxter Healthcare Corporation verwendet. Baxter hat keine Kontrolle über die Variabilität, Toleranzen oder mechanische Festigkeit dieser Produkte oder über Änderungen, die an diesen Produkten von Zeit zu Zeit vorgenommen werden. Baxter kann daher nicht gewährleisten, dass Dialyseprodukte anderer Hersteller, wenn sie an Produkte von Baxter angeschlossen werden, ordnungsgemäß funktionieren.

Gebrauchsanleitung

Auf aseptische Arbeitsweise achten.

1. Schaffen Sie einen sterilen Arbeitsbereich. Platzieren Sie den Adapter auf dieser sterilen Arbeitsfläche.
2. Informationen zur allgemeinen Vorbereitung des Katheters finden Sie gegebenenfalls in der Gebrauchsanleitung des Katheters.
3. Bringen Sie die Katheterklemme am Katheter an.
4. Reinigen Sie den Anschluss 1 Minute lang mit steriler, in Povidon-Jod getränkter Gaze.
5. Legen Sie Katheteradapter und Katheterschlauch 5 Minuten lang in Povidon-Jodlösung ein.
6. Falls zutreffend, gebrauchten Adapter entfernen, indem Sie den Katheter direkt unter dem Adapter mit einer sterilen Schere abschneiden. Achten Sie beim Abschneiden auf gerade Kanten, das erleichtert die Befestigung.
7. Führen Sie den Katheter in das kleine, nicht mit Gewinde versehene Ende der Überwurfmutter ein. Schieben Sie die Überwurfmutter so über den Katheter, dass das Ende des Katheters frei herausragt.
8. Führen Sie den Katheteradapter bis zum Ansatz in den Katheter ein. Überprüfen Sie nach dem Einführen den Katheterschlauch an der Einführstelle und überzeugen Sie sich, dass der Adapter dicht abschließt und der Katheter keine Spalten oder Risse hat. Der Adapter muss korrekt im Katheter sitzen und sollte sich auch dann nicht im Katheter bewegen, wenn auf den Adapter Zug ausgeübt wird.
9. Schieben Sie die Überwurfmutter entlang dem Katheter zum Adapter. Schrauben Sie die Überwurfmutter auf den Adapter, bis sie fest sitzt.
10. Legen Sie den Katheter mit dem Adapter für weitere 5 Minuten in Povidon-Jodlösung ein.
11. Verschließen Sie den Adapter mit der Verschlusskappe für PD-Katheteradapter oder befestigen Sie das Überleitungssystem.
12. Entfernen Sie die Katheterklemme.
13. Entsorgen Sie den gebrauchten Adapter gemäß den örtlichen Abfallentsorgungsvorschriften.

Nicht wiederverwenden

Gebrauchsanleitung lesen

Pyrogenfrei

Nicht verwenden, wenn die Packung beschädigt ist.

RT Bei Raumtemperatur lagern

Hersteller

STERILE EO Sterilisiert mit Ethylenoxid

SW-30-01-057

Vergrendelbare titanium adapter voor PD-katheter

dut

Beschrijving

Deze adapter is een dubbelsluitende vrouwelijke lueradapter met een uit twee stukken bestaande, gecombineerde katheterconnector met compressiepasvorm/karteling. De adapter wordt gebruikt om de PD-katheter aan te sluiten op een transferset met vergrendelingsconnector. Deze adapter is compatibel met peritoneale dialysekatheters met nominale afmetingen met een binnendiameter van 2,6 mm/buitendiameter van 5 mm en een binnendiameter van 3,5 mm/buitendiameter van 5,1 mm.

Steriel, pyrogeenvrij, gesteriliseerd met ethyleenoxide.

Indicaties voor gebruik: De vergrendelbare titanium adapter voor de peritoneale dialysekatheter is bedoeld voor bevestiging van de peritoneale katheterlijn aan de Baxter-transferset die tijdens de peritoneale dialysetherapie wordt gebruikt.

Contra-indicaties

Gebruik geen povidonjodium om de transferset aan te sluiten op de titanium adapter van Baxter bij een bekende voorgeschiedenis van allergische reactie op jodium. Gebruik andere ontsmettingsmiddelen of antiseptica die geen jodium, waterstofperoxide, alcohol of bleekmiddelen bevatten.

Waarschuwingen

Pas een aseptische techniek toe. Besmetting van enig onderdeel van het vloeistoftraject kan leiden tot peritonitis.

Dit product is bedoeld voor eenmalige verbinding met de peritoneale dialysekatheter van de patiënt. Dit product niet hergebruiken. Als dit medische hulpmiddel opnieuw wordt gebruikt of gesteriliseerd, kan dit leiden tot besmetting en tot een verstoorde werking of aantasting van de structurele integriteit van het hulpmiddel.

Het wordt aanbevolen de schildklierfunctie te controleren bij patiënten met kleine inloopvolumes peritoneaal dialysaat, meestal zuigelingen en kinderen. Om blootstelling aan jodium te minimaliseren, laat u voorafgaand aan de volgende vulcyclus de inhoud van de peritoneale holte naar de afvoerhouder lopen, wanneer dit klinisch mogelijk is.

Niet gebruiken indien de zak beschadigd is.

Besmetting op het moment van inbrenging van de adapter kan leiden tot peritonitis. De adapter moet volgens onderstaande procedure in een steriele katheter worden ingebracht.

Veel dialyseproducten van andere fabrikanten worden gebruikt met apparatuur of wegwerpproducten van Baxter Healthcare Corporation. Baxter heeft geen controle over variabiliteit, toleranties, mechanische sterkte of eventueel aangebrachte wijzigingen in deze producten. Baxter kan daarom niet garanderen dat dialyseproducten van andere fabrikanten toereikend werken wanneer deze in combinatie met Baxter-producten worden gebruikt.

Gebruiksaanwijzing

Aseptische techniek toepassen

1. Zorg voor een aseptisch veld. Plaats de adapter in het aseptisch veld.
2. In voorkomende gevallen raadpleegt u voor informatie over de algemene procedure van voorbereiding van de katheter de gebruiksaanwijzing van de katheter.
3. Klem de katheter af.
4. Wrijf de aansluiting gedurende één minuut af met steriel gaas met povidonjodium.
5. Dompel de katheteradapter en de katheterlijn gedurende 5 minuten onder in povidonjodium.
6. Verwijder de gebruikte adapter, wanneer dit van toepassing is, door de katheter direct onder de adapter af te knippen met een steriele schaar. Zorg bij het afknippen van de katheter voor rechte randen om de plaatsing te vergemakkelijken.
7. Leid het korte uiteinde van de vergrendelingsadapterhuls (zonder schroefdraad) over de katheter. Schuif de huls over de katheter zodat het uiteinde van de katheter bloot komt te liggen.
8. Breng de katheteradapter tot aan de schouder in de katheter in. Inspecteer de katheterlijn na inbrenging op de inbrenglocatie om er zeker van te zijn dat de adapter volledig ingebracht is, en er geen sprake is van splijting of scheuren in de katheter. De adapter moet precies op de katheter passen. Als er aan de adapter wordt getrokken, mag dit niet leiden tot slippen van de katheter.
9. Schuif de huls terug over de katheter in de richting van de adapter. Schroef de huls op de adapter, tot deze stevig op zijn plaats zit.
10. Dompel de katheter met adapter en de katheterlijn nogmaals gedurende 5 minuten onder in povidonjodium.
11. Plaats de vergrendelingsdop voor de peritoneale dialysekatheteradapter op de adapter of sluit de transferset aan.
12. Verwijder de katheterklem.
13. Verwijder de gebruikte adapter overeenkomstig lokale voorschriften.

Niet hergebruiken

Gebruiksaanwijzing raadplegen

Pyrogeenvrij

Niet gebruiken indien de verpakking beschadigd is.

RT Bewaren bij kamertemperatuur

Fabrikant

STERILE EO Gesteriliseerd met ethyleenoxide

Adaptateur en titane pour cathéter de D.P. avec bague de serrage

fre

Description

Cet adaptateur est un adaptateur luer-lock femelle à double joint doté d'un connecteur pour cathéter deux pièces cannelé/à compression. Il permet de connecter le cathéter de D.P. à une ligne de transfert de solution avec une bague de serrage. Cet adaptateur est compatible avec des cathéters de dialyse péritonéale présentant des mesures nominales de 2,6 mm D.I. / 5 mm D.E. et 3,5 mm D.I. / 5,1 mm D.E.

Stérile, apyrogène. Stérilisé à l'oxyde d'éthylène.

Indications et utilisation : L'adaptateur en titane pour cathéter de dialyse péritonéale avec bague de serrage est conçu pour fixer la tubulure du cathéter de D.P. à la ligne de transfert Baxter utilisée pendant une dialyse péritonéale.

Contre-indications

Ne pas utiliser de povidone iodée pour connecter la ligne de transfert à l'adaptateur en titane Baxter en cas d'antécédents connus de réaction allergique à l'iode. Utiliser d'autres désinfectants ou antiseptiques ne contenant pas d'iode, d'eau oxygénée, d'alcool ni d'eau de javel.

Avertissements

Procéder de manière aseptique. Une contamination d'une partie quelconque du trajet du liquide peut entraîner une péritonite.

Ce dispositif est conçu pour une connexion unique au cathéter de dialyse péritonéale du patient. Ne pas le réutiliser. La réutilisation ou le retraitement de ce dispositif peut entraîner la contamination, le dysfonctionnement ou la perte d'intégrité structurelle du dispositif.

Il est conseillé de contrôler la fonction thyroïdienne chez les patients présentant un faible volume de dialysat péritonéal, généralement les nourrissons et les enfants. Pour limiter l'exposition à l'iode, laisser s'écouler le contenu de la cavité péritonéale dans la poche de drainage avant de lancer le cycle de remplissage suivant à chaque fois que l'état clinique du patient le permet.

Ne pas utiliser si la poche est endommagée.

Une contamination au moment de l'insertion de l'adaptateur peut entraîner une péritonite. L'adaptateur doit être inséré dans un cathéter stérile selon la procédure décrite ci-dessous.

Différents produits de dialyse distribués par d'autres sociétés peuvent être utilisés avec le matériel ou les consommables de Baxter Healthcare Corporation. Baxter n'est pas responsable des variabilités, des tolérances, de la résistance mécanique ou des modifications pouvant parfois survenir sur ces produits. C'est pourquoi Baxter ne peut garantir le bon fonctionnement des produits de dialyse d'autres fabricants lorsqu'ils sont connectés à ses produits.

Mode d'emploi

Procéder de manière aseptique

1. Créer un champ stérile. Placer l'adaptateur sur le champ stérile.
2. Pour connaître la procédure générale de préparation du cathéter, consulter les instructions d'utilisation de ce dernier, le cas échéant.
3. Clamper le cathéter.
4. Nettoyer la connexion avec une compresse de gaze stérile imbibée de povidone iodée pendant 1 minute.
5. Faire tremper l'adaptateur et la tubulure du cathéter dans une solution de povidone iodée pendant 5 minutes.
6. Lorsque cela est nécessaire, retirer l'adaptateur usagé en coupant le cathéter à l'aide de ciseaux stériles juste sous l'adaptateur. Couper le cathéter pour obtenir des bords droits et faciliter la mise en place.
7. Insérer le petit embout non fileté de la bague de serrage dans le cathéter. Faire coulisser jusqu'à ce que l'extrémité du cathéter dépasse.
8. Insérer l'adaptateur dans le cathéter jusqu'au rebord du pas de vis. Après insertion, inspecter la tubulure du cathéter à l'endroit de l'insertion pour vérifier que l'adaptateur est entièrement en place et que le cathéter ne présente ni déchirure ni accroc. L'adaptateur doit s'ajuster parfaitement au cathéter et ne pas glisser dans le cathéter si l'on tire dessus.
9. Faire coulisser à nouveau la bague de serrage le long du cathéter jusqu'à l'adaptateur. Visser la bague de serrage sur l'adaptateur jusqu'à ce qu'elle tienne fermement.
10. Faire tremper le cathéter avec l'adaptateur dans une solution de povidone iodée pendant 5 minutes supplémentaires.
11. Bloquer l'adaptateur avec le capuchon de serrage pour adaptateur de cathéter pour dialyse péritonéale ou attacher la ligne de transfert.
12. Retirer le clamp du cathéter.
13. Jeter l'adaptateur usagé conformément aux réglementations locales en matière de déchets.

Ne pas réutiliser

Consulter le mode d'emploi

Apyrogène

Ne pas utiliser si l'emballage est endommagé.

RT A conserver à température ambiante

Fabricant

STERILE EO Stérilisé à l'oxyde d'éthylène

SW-30-01-057

spa

Adaptador de titanio para catéter de DP

Descripción

Este adaptador es un adaptador Luer lock hembra de doble cierre con un conector de dos piezas que combina el ajuste y el roscado al catéter. El adaptador se utiliza para conectar el catéter de diálisis peritoneal al equipo de transferencia mediante dicho conector de cierre. Este adaptador es compatible con catéteres de diálisis peritoneal de medidas nominales de 2,6 mm de diámetro interno/5 mm de diámetro externo y 3,5 mm de diámetro interno/5,1 mm de diámetro externo.

Estéril y apirógeno, esterilizado con óxido de etileno.

Indicaciones de uso: El adaptador de titanio de cierre para el catéter de diálisis peritoneal está diseñado para fijar el tubo del catéter peritoneal al equipo de transferencia de Baxter durante el tratamiento de diálisis peritoneal.

Contraindicaciones

No utilizar povidona yodada para conectar el equipo de transferencia al adaptador de titanio de Baxter si tiene un historial conocido de reacción alérgica al yodo. Utilizar otros desinfectantes o agentes antisépticos que no contengan yodo, agua oxigenada, alcohol o lejía.

Advertencias

Utilizar una técnica aséptica. La contaminación de cualquier parte del circuito de líquidos puede producir una peritonitis.

Este dispositivo está diseñado para conectarse una sola vez al catéter de diálisis peritoneal del paciente. No reutilizar este dispositivo. La reutilización o el reprocesamiento de este dispositivo puede provocar la contaminación y afectar al funcionamiento del dispositivo o a la integridad de la estructura.

Se recomienda que se controle la función tiroidea en pacientes con bajos volúmenes de infusión, especialmente en bebés y niños. Para minimizar la exposición al yodo se debe drenar el contenido de la cavidad peritoneal al receptáculo de drenaje antes de iniciar el siguiente ciclo de llenado cuando sea clínicamente posible.

No utilizar si la bolsita está dañada.

La contaminación en el momento de la inserción del adaptador puede producir una peritonitis. El adaptador debe insertarse en un catéter estéril según el procedimiento siguiente.

Muchos productos de diálisis de otros fabricantes se utilizan con equipos o dispositivos desechables de Baxter Healthcare Corporation. Baxter no tiene ningún control sobre la variabilidad, la tolerancia, la resistencia mecánica o los cambios que pudieran producirse eventualmente en estos productos. Por lo tanto, Baxter no puede garantizar el correcto funcionamiento de los productos de diálisis de otros fabricantes cuando se conectan a sus productos.

Instrucciones de uso

Utilizar una técnica aséptica.

1. Crear un campo aséptico. Colocar el adaptador en el campo aséptico.
2. Para el procedimiento general de preparación del catéter, consultar las instrucciones de uso del catéter cuando sea aplicable.
3. Pinzar el catéter.
4. Frotar la conexión con povidona yodada utilizando una gasa estéril durante 1 minuto.
5. Sumergir el adaptador del catéter y el tubo del catéter en una solución de povidona yodada durante 5 minutos.
6. Cuando corresponda, retirar el adaptador usado cortando el catéter con tijeras estériles inmediatamente por debajo del adaptador. Cortar el catéter para conseguir unos bordes rectos que faciliten la colocación.
7. Introducir el catéter por el orificio del extremo más pequeño y sin rosca de la pieza exterior del adaptador. Girar la pieza exterior hasta exponer el extremo del catéter.
8. Insertar en la luz del catéter la pieza interior del adaptador hasta el tope. Tras insertarlo, inspeccionar el tubo del catéter en el lugar de la inserción para verificar que el adaptador está completamente encajado y que el catéter no presenta ni grietas ni fisuras. El adaptador debe encajar perfectamente en el catéter; al tirar del adaptador no se debe producir el deslizamiento de éste sobre el catéter.
9. Deslizar la pieza exterior del adaptador hacia la interior, enroscando hasta que ambas queden firmemente ajustadas.
10. Sumergir el catéter con el adaptador en una solución de povidona yodada durante 5 minutos más.
11. Cubrir el adaptador con la tapa de cierre del adaptador para catéter de diálisis peritoneal o acoplar el equipo de transferencia.
12. Retire la pinza del catéter.
13. Eliminar el adaptador usado según la normativa local.

Un solo uso

Consultar las instrucciones de uso

Apirógeno

No utilizar si el envase está dañado.

RT Conservar a temperatura ambiente

Fabricante

STERILE EO Esterilizado con óxido de etileno

ita

Adattatore al titanio per catetere peritoneale con sistema di bloccaggio

Descrizione

Questo è un adattatore per catetere Luer lock femmina a doppio sistema di bloccaggio combinato a compressione e a vite. L'adattatore viene usato per connettere il catetere per dialisi peritoneale al set di trasferimento della soluzione provvisto di connettore con sistema di bloccaggio. L'adattatore è compatibile con cateteri per dialisi peritoneale delle seguenti misure nominali: DI 2,6 mm / DE 5 mm, e DI 3,5 mm / DE 5,1 mm.

Sterile e apirogeno. Sterilizzato con ossido di etilene.

Indicazioni per l'uso: l'adattatore al titanio per catetere per dialisi peritoneale è progettato per fissare il tubo del catetere peritoneale al set di trasferimento di Baxter durante la dialisi peritoneale.

Controindicazioni

Non usare iodopovidone quando si collega il set di trasferimento all'adattatore al titanio Baxter in presenza di un'anamnesi nota di reazioni allergiche allo iodio. Utilizzare altri disinfettanti o antisettici non contenenti iodio, perossido di idrogeno, alcool o candeggina.

Avvertenze

Adottare una tecnica asettica. La contaminazione di qualsiasi porzione del percorso del liquido può dar luogo a peritonite.

Il dispositivo è concepito per una singola connessione al catetere per dialisi peritoneale del paziente. Non riutilizzare il dispositivo. Il riutilizzo o la rilavorazione del dispositivo può comportare contaminazione e compromissione delle funzioni o dell'integrità strutturale del dispositivo stesso.

Si raccomanda il monitoraggio della funzione tiroidea in pazienti con piccoli volumi di riempimento di dialisato peritoneale, in genere lattanti o bambini. Per ridurre al minimo l'esposizione allo iodio, drenare il contenuto della cavità peritoneale nel recipiente di drenaggio prima di avviare il successivo ciclo di riempimento, ove clinicamente possibile.

Non utilizzare se la busta è danneggiata.

La contaminazione al momento dell'inserimento dell'adattatore può dar luogo a peritonite. L'adattatore deve essere inserito in un catetere sterile seguendo la procedura descritta sotto.

Numerosi prodotti per dialisi di altri produttori vengono utilizzati con apparecchiature o dispositivi monouso di Baxter Healthcare Corporation. Baxter non esercita alcun controllo sulla variabilità, sulle tolleranze, sulla resistenza meccanica o sulle modifiche che possono essere apportate di tanto in tanto a questi prodotti. Baxter non può pertanto assicurare un funzionamento soddisfacente dei prodotti per dialisi di altri produttori collegati ai propri prodotti.

Istruzioni per l'uso

Adottare una tecnica asettica.

1. Preparare un campo sterile. Collocare l'adattatore nel campo sterile.
2. Per la procedura generale di preparazione del catetere, consultare le istruzioni per l'uso del catetere, se necessario.
3. Clampare il catetere.
4. Pulire la connessione per 1 minuto con una garza sterile imbevuta di iodopovidone.
5. Immergere l'adattatore e il tubo del catetere in una soluzione di iodopovidone per 5 minuti.
6. Se necessario, rimuovere l'adattatore usato tagliando il catetere con forbici sterili subito sotto di esso. Tagliare il catetere in modo da avere margini netti per facilitare il posizionamento.
7. Inserire il catetere nell'estremità piccola, non filettata, del manicotto dell'adattatore con sistema di bloccaggio. Far scivolare il manicotto sul catetere fino a esporre l'estremità del catetere.
8. Inserire l'adattatore nel catetere fino alla spalla. Dopo l'inserimento, ispezionare il tubo del catetere nel punto di inserimento per verificare che l'adattatore sia completamente posizionato e il catetere non presenti fenditure o rotture. L'adattatore dovrebbe essere posizionato strettamente nel catetere; esercitando una trazione sull'adattatore, questo non dovrebbe scivolare sul catetere.
9. Far scivolare indietro il manicotto lungo il catetere verso l'adattatore. Avvitare il manicotto sull'adattatore finché non è saldamente posizionato.
10. Immergere il catetere con l'adattatore in una soluzione di iodopovidone per altri 5 minuti.
11. Chiudere l'adattatore con l'apposito cappuccio di blocco o collegarlo al set di trasferimento.
12. Rimuovere la clamp del catetere.
13. Smaltire l'adattatore usato in conformità con le linee guida locali per lo smaltimento.

Non riutilizzare

Consultare le istruzioni per l'uso

Apirogeno.

Non utilizzare se la confezione è danneggiata.

RT Conservare a temperatura ambiente

Produttore

STERILE EO Sterilizzato con ossido di etilene.

SW-30-01-057

Titaniumadapter til PD-kateter, låsbar

dan

Beskrivelse

Denne adapter er en dobbeltforseglende hun luer-lock-adapter med en todelt kombineret kompressions-/riflet kateterkobling. Adapteren anvendes til at koble PD-kateteret til et slangesæt med låsbar kobling. Adapteren kan anvendes sammen med PD-katetre med følgende nominelle mål: Indv. diam. 2,6 mm/udv. diam. 5 mm og indv. diam. 3,5 mm/udv. diam. 5,1 mm.

Steril, pyrogenfri, steriliseret med ethylenoxid.

Indikationer for brug: Den låsbare titaniumadapter til PD-kateter er beregnet til at fastgøre PD-kateteret til Baxter-slangesættet, som anvendes under peritonealdialysebehandlingen.

Kontraindikationer

Brug ikke povidon-jod til at forbinde slangesættet til Baxter titaniumadapteren, hvis der er kendte allergiske reaktioner mod jod i anamnesen. Anvend andre desinfektionsmidler eller antiseptiske midler, som ikke indeholder jod, hydrogenperoxid, alkohol eller blegemiddel.

Advarsler

Brug aseptisk teknik. Kontaminering af væskebanens dele kan medføre peritonitis.

Dette udstyr er beregnet til tilslutning til patientens PD-kateter én gang. Udstyret må ikke genanvendes. Genbrug eller forarbejdning af dette udstyr kan medføre kontaminering og nedsat funktion eller ændring i konstruktionen af udstyret.

Det anbefales, at skjoldbruskkirtelfunktionen overvåges hos patienter med små PD-indløbsvolumener, typisk spædbørn og børn. For at minimere eksponering for jod skal indholdet i bughulen drænes til udløbsposen før påbegyndelse af næste indløbscyklus, hvor dette er klinisk muligt.

Må ikke anvendes, hvis posen er beskadiget.

Kontaminering på tidspunktet for adapterens tilslutning kan medføre peritonitis. Adapteren skal sættes på et sterilt kateter i henhold til nedenstående fremgangsmåde.

Mange dialyseprodukter fra andre producenter bruges sammen med udstyr eller engangsartikler fra Baxter Healthcare Corporation. Baxter har ikke kontrol over disse produkters variabilitet, tolerance, mekaniske styrke eller ændringer, der foretages fra tid til anden. Derfor kan Baxter ikke garantere, at andre producenters dialyseprodukter fungerer tilfredsstillende, når de anvendes sammen med Baxters produkter.

Brugsanvisning

Brug aseptisk teknik

1. Brug et aseptisk område. Placér adapteren i det aseptiske område.
2. Der henvises til kateterets brugsanvisning for generelle oplysninger om klargøring af kateteret, når det er relevant.
3. Afklem kateteret.
4. Skrub koblingen med povidon-jod med steril gaze i 1 minut.
5. Læg kateteradapteren og kateterslangen i blød i povidon-jodopløsning i 5 minutter.
6. Hvor dette er relevant, afmonteres den brugte adapter ved at klippe kateteret over med en steril saks umiddelbart under adapteren. Tilskær kateteret for at sikre lige kanter, der letter tilslutningen.
7. Før adapterens smalle låseende uden gevind ned over kateteret. Pres koblingen opad, indtil kateteret er synligt.
8. Pres kateteradapteren ind i kateteret. Efter indføringen skal kateterslangen efterses ved indføringsstedet for at sikre, at adapteren er korrekt tilsluttet, og at der hverken er revner eller rifter i kateteret. Adapteren skal passe perfekt til kateteret. Hvis man trækker i adapteren, må dette ikke give anledning til, at kateteret går løs.
9. Pres adapteren tilbage mod kateterets ende og den anden del af adapteren. Skru delene sammen, så de sidder fast.
10. Læg kateteret med adapteren i blød i povidon-jodopløsning i yderligere 5 minutter.
11. Luk adapteren med sterilbeskyttelseshætte til titaniumadapter eller tilslut slangesættet.
12. Fjern kateterklemmen.
13. Kassér den brugte adapter i overensstemmelse med de lokale retningslinjer for bortskaffelse af affald.

Må ikke genanvendes

Se brugsvejledningen

Pyrogenfri

Må ikke anvendes, hvis pakningen er beskadiget.

RT Opbevares ved stuetemperatur

Fremstiller

STERILE EO Steriliseret med ethylenoxid

Låsbar PD-kateteradapter av titan

swe

Beskrivning

Denna adapter är en dubbelt förslutande hon-Luer-lockadapter med en 2-delad kombination av kompressionsanpassad/hullingförsedd kateterkoppling. Adaptern används för att ansluta PD-katetern till ett patientaggregat med låsbar koppling. Adaptern är kompatibel med peritonealdialyskatetrar med de nominella måtten 2,6 mm ID (innerdiameter)/5 mm YD (ytterdiameter) och 3,5 mm ID(innerdiameter)/5,1 mm YD(ytterdiameter).

Steril, icke-pyrogen. Steriliserad med etylenoxid.

Indikationer: Den låsbara titanadaptern för peritonealdialyskatetrar är avsedd att ansluta peritonealkateterslangen till Baxters patientaggregat som används vid peritonealdialysbehandling.

Kontraindikationer

Använd inte povidonjod för att ansluta patientaggregatet till Baxters titanadapter om det finns känd allergisk reaktion mot jod i anamnesen. Använd då andra desinfektionsmedel eller antiseptiska medel som inte innehåller jod, väteperoxid, alkohol eller blekmedel.

Varningar

Använd aseptisk teknik. Kontamination av någon del av vätskebanan kan leda till peritonit.

Denna produkt är avsedd för engångsanslutning till patientens peritonealdialyskateter. Återanvänd inte denna produkt. Återanvändning eller omarbetning av produkten kan leda till kontamination och äventyra produktens funktion eller strukturella integritet.

Det rekommenderas att sköldkörtelfunktionen övervakas hos patienter med små fyllnadsvolymer av peritonealdialysvätska, t.ex. spädbarn och barn. För att minimera jodexponeringen ska innehållet i bukhålan tömmas till behållaren innan nästa fyllningscykel inleds, när detta är kliniskt möjligt.

Använd inte produkten om påsen är skadad.

Kontamination vid adapterinförandet kan leda till peritonit. Adaptern ska föras in i en steril kateter enligt nedanstående beskrivning.

Många dialysprodukter som är tillgängliga från andra tillverkare används tillsammans med utrustning eller förbrukningsmateriel från Baxter Healthcare Corporation. Baxter har ingen kontroll över variabilitet, toleranser, mekanisk styrka på eller förändringar av dessa produkter som från tid till annan kan inträffa. Därför kan Baxter inte garantera att andra tillverkares dialysprodukter kommer att fungera på ett tillfredsställande sätt när de ansluts till Baxters produkter.

Anvisningar för användning

Använd aseptisk teknik

1. Skapa ett aseptiskt fält. Placera adaptern i det aseptiska fältet.
2. För allmän procedur för förberedelse av katetern, se kateterns bruksanvisning om tillämpligt.
3. Sätt en klämma på katetern.
4. Skrubba kopplingen med povidonjod med hjälp av en steril kompress i 1 minut.
5. Blötlägg kateteradaptern och kateterslangen i povidonjodlösning i 5 minuter.
6. Om tillämpligt, avlägsna den använda adaptern genom att klippa av katetern med en steril sax omedelbart nedanför adaptern. Klipp/skär av katetern så att kanterna blir raka för att underlätta placeringen.
7. För in den lilla, ogängade änden av adapterns låshylsa på katetern. Skjut upp hylsan på katetern så att kateterändеn exponeras.
8. För in kateteradaptern i katetern fram till adapterns bredaste del. Inspektera kateterslangen vid införingsstället efter införandet för att kontrollera att adaptern är korrekt placerad och att det inte finns några sprickor eller revor på katetern. Adaptern ska sitta ordentligt fast på katetern. Om man drar i adaptern får den inte glida på katetern.
9. Skjut tillbaka hylsan på katetern, ned mot adaptern. Skruva fast hylsan på adaptern tills den sitter ordentligt fast.
10. Blötlägg katetern med adaptern i povidonjodlösning i ytterligare 5 minuter.
11. Sätt ett adapterskydd på adaptern med låshylsan för peritonealdialyskateterns adapter eller sätt fast patientaggregatet.
12. Avlägsna kateterklämman.
13. Kassera den använda adaptern enligt lokala riktlinjer för avfallshantering.

Får ej återanvändas

Se bruksanvisningen

Icke-pyrogen

Använd inte produkten om förpackningen är skadad.

RT Förvaras i rumstemperatur

Tillverkare

STERILE EO Steriliserad med etylenoxid

SW-30-01-057

Adaptador de titânio com fecho para cateter de DP

por

Descrição

Este adaptador é um adaptador de duplo bloqueio Luer fêmea, com um conector de cateter de duas peças de combinação encaixe com pressão/rosca. O adaptador é utilizado para ligar o cateter de DP a um conjunto de transferência de solução com um conector bloqueante. Este adaptador é compatível com cateteres de diálise peritoneal, com as medidas nominais de 2,6 mm DI / 5 mm DE e 3,5 mm DI / 5,1 mm DE.

Estéril e apirogénico, esterilizado por óxido de etileno.

Indicações de utilização: O adaptador de titânio com fecho para cateter de diálise peritoneal destina-se a assegurar a ligação do tubo do cateter peritoneal ao conjunto de transferência da Baxter utilizado durante o tratamento de diálise peritoneal.

Contraindicações

Não utilizar iodopovidona para ligar o conjunto de transferência ao adaptador de titânio da Baxter se forem conhecidos antecedentes de reação alérgica ao iodo. Utilizar outros desinfetantes ou agentes antissépticos sem iodo, peróxido de hidrogénio, álcool ou lixívia.

Advertências

Utilizar técnica asséptica. A contaminação de qualquer parte do circuito de fluidos pode provocar peritonite.

Este dispositivo destina-se a ser ligado uma só vez ao cateter de diálise peritoneal do doente. Não reutilizar este dispositivo. A reutilização ou o reprocessamento deste dispositivo pode conduzir à contaminação e comprometer a sua função ou integridade estrutural.

Recomenda-se a monitorização da função tiroideia nos doentes com pequenos volumes de infusão de solução de diálise peritoneal, normalmente em lactentes e crianças. Para minimizar a exposição ao iodo, drene o conteúdo da cavidade peritoneal para a bolsa de drenagem antes de iniciar o ciclo de infusão seguinte, sempre que seja clinicamente possível.

Não utilizar se a bolsa estiver danificada.

A contaminação na inserção do adaptador pode provocar peritonite. O adaptador deve ser inserido num cateter estéril, seguindo os procedimentos abaixo.

Muitos produtos de diálise de outros fabricantes são utilizados com equipamento ou material descartável da Baxter Healthcare Corporation. A Baxter não tem qualquer controlo sobre a variabilidade, tolerância, força mecânica ou alterações que possam vir a ocorrer nestes produtos. Por conseguinte, a Baxter não pode assegurar que os produtos de diálise de outros fabricantes, quando ligados aos seus produtos, funcionem de forma satisfatória.

Instruções de uso

Utilizar técnica asséptica.

1. Criar um campo asséptico. Colocar o adaptador no campo asséptico.
2. Para obter informações sobre os procedimentos gerais de preparação do cateter, consultar as instruções de uso do cateter quando aplicável.
3. Colocar um clampe no cateter.
4. Esfregar a ligação com iodopovidona, utilizando uma gaze estéril, durante 1 minuto.
5. Mergulhar o adaptador e o tubo do cateter em solução de iodopovidona durante 5 minutos.
6. Quando for necessário remover o adaptador usado, cortar o cateter imediatamente abaixo do adaptador, utilizando uma tesoura estéril. Cortar o cateter, de forma a ficar com as extremidades retas para facilitar a fixação.
7. Inserir a pequena extremidade sem rosca do anel do adaptador bloqueante no cateter. Deslizar o anel para expor a extremidade do cateter.
8. Inserir o adaptador do cateter no interior do mesmo até ao topo. Depois de inserido, inspecionar o respetivo tubo no local da inserção para verificar se o adaptador está completamente fixado e que o cateter não apresenta dobras nem rasgões. O adaptador deverá ficar perfeitamente ajustado no cateter; assim, se puxar o adaptador, este não deverá deslizar no cateter.
9. Deslizar o anel ao longo do cateter, no sentido do adaptador. Apertar o anel ao adaptador até fixar firmemente.
10. Mergulhar o cateter com o adaptador em solução de iodopovidona durante mais 5 minutos.
11. Tapar o adaptador com a tampa de proteção para o adaptador do cateter de diálise peritoneal ou ligar o conjunto de transferência.
12. Retirar o clampe do cateter.
13. Eliminar o adaptador usado de acordo com as diretivas locais para a eliminação de resíduos.


Não reutilizar


Apirogénico

Armazenar à temperatura ambiente

Esterilizado com óxido de etileno


Consultar as instruções de utilização


Não utilizar caso a embalagem esteja danificada.


Fabricante

Titanium Adapteri PD katetriin

fin

Kuvaus

Tämä adapteri on kaksoiskierteellinen naaraspuoleinen Luerlock-adapteri, jossa on myös kaksiosainen väkäsliitäntä katetriin. Adapterilla yhdistetään PD-katetri nesteensiirtolaitteen liittimeen. Tämä adapteri on yhteensopiva PD-katetrien kanssa, joiden nimelliset mitat ovat sisähalk. 2,6 mm / ulkohalk. 5 mm ja sisähalk. 3,5 mm / ulkohalk. 5,1 mm.

Steriili, pyrogeeniton. Steriloitu etyleenioksidilla.

Käyttöaiheet: Peritoneaalidialyysikatetriin liitettävä Titanium-adapteri on tarkoitettu peritoneaalikatetrin letkun liittämiseen Baxter-siirtolaitteeseen, jota käytetään peritoneaalidialyysihoidon aikana.

Vasta-aiheet

Älä käytä povidonijodia siirtolaitteen liittämiseen Baxter Titanium -adapteriin, jos jodista on tiettävästi tullut aiemmin allerginen reaktio. Käytä muita desinfiointiaineita tai antiseptisiä aineita, jotka eivät sisällä jodia, vetyperoksidia, alkoholia tai valkaisuainetta.

Varoitukset

Käytä aseptista tekniikkaa. Nestereitin minkä tahansa osan kontaminaatio voi aiheuttaa peritoniitin.

Tämä laite on tarkoitettu kertaliitäntään potilaan peritoneaalidialyysikatetriin. Tämä laite on kertakäyttöinen. Tämän laitteen uudelleenkäyttö tai -käsittely voi johtaa kontaminaatioon ja heikentää laitteen toimintaa tai rakennetta.

Kilpirauhasen toimintaa on valvottava niiden potilaiden kohdalla, joilla täyttömäärät ovat pieniä, kuten sylilapsilla ja lapsilla. Jodialtistuksen minimoimiseksi vatsaontelo on tyhjennettävä nesteestä tyhjennyspussiin ennen seuraavaa nesteen sisäänvalutusta aina kun se on kliinisesti mahdollista.

Älä käytä, jos pussi on vaurioitunut.

Kontaminaatio adapterin liittämisen yhteydessä voi aiheuttaa peritoniitin. Adapteri on yhdistettävä steriiliin katetriin seuraavien ohjeiden mukaisesti.

Baxter Healthcare Corporationin valmistamien laitteiden ja kertakäyttötarvikkeiden kanssa käytetään useita muiden valmistajien dialyysitarvikkeita. Baxter ei voi valvoa näiden tarvikkeiden vaihtelevuutta, mekaanista vahvuutta tai muutoksia, joita näihin tuotteisiin aika ajoin tehdään. Tästä syystä Baxter ei voi taata, että muiden valmistajien dialyysitarvikkeet toimivat oletetusti, kun ne on kytketty Baxterin laitteisiin ja tarvikkeisiin.

Käyttöohjeet

Käytä aseptista tekniikkaa

1. Luo aseptinen ympäristö. Aseta adapteri steriilille pöydälle.
2. Katetrin yleiset valmisteluohjeet ovat katetrin käyttöohjeissa.
3. Sulje katetri.
4. Pyyhi liitäntää steriiliin sideharsoon lisätyllä povidonijodilla minuutin ajan.
5. Liota katetriadapteria ja katetriletkua povidonijodiliuoksessa 5 minuutin ajan.
6. Poista käytetty adapteri tarvittaessa leikkaamalla katetri steriileillä saksilla aivan adapterin alapuolelta. Leikkaa katetriin suorat reunat, jotta adapteri on helpompi asettaa.
7. Työnnä adapterin holkin kapeaa, kierteetöntä päätä katetriin. Liu'uta holkkia katetria ylös, jotta katetrin pää paljastuu.
8. Työnnä katetriadapteri katetrin ulkonemaan saakka. Tarkista asennuksen jälkeen, että katetrin letku on asetuspaikassa ja varmista, että adapteri on asettunut hyvin paikoilleen ja ettei katetri ole haljennut tai revennyt. Adapterin pitäisi istua tiiviisti katetriin. Adapterin vetämisen ei pitäisi saada katetria liukumaan.
9. Liu'uta holkki katetria pitkin adapteriin asti. Kierrä holkki tiiviisti adapteriin.
10. Liota katetria ja adapteria ja katetriletkua povidonijodiliuoksessa vielä 5 minuutin ajan.
11. Aseta Titanium-adapterin suojakorkki tai kiinnitä siirtolaite.
12. Poista katetrin sulkija.
13. Hävitä käytetty adapteri paikallisten määräysten mukaisesti.


Kertakäyttöinen


Lue käyttöohjeet


Pyrogeeniton


Älä käytä, jos pakkaus on vaurioitunut.

Säilytettävä huoneenlämmössä


Valmistaja

Steriloitu etyleenioksidilla

SW-30-01-057

Titaniumadapter til PD-kateter, låsbar

nor

Beskrivelse

Denne adapteren er en dobbeltforseglende hunn-luer-lock-adapter med en kateterkobling i 2 deler med en kombinasjon av kompresjonstilpasning/mothaker. Adapteren brukes til å koble PD-kateteret til et MiniSett med låsekobling. Denne adapteren er kompatibel med peritonealdialysekatetre med nominelle mål på 2,6 mm ID / 5 mm YD og 3,5 mm ID / 5,1 mm YD.

Steril, pyrogenfri væskebane. Sterilisert med etylenoksid.

Indikasjoner for bruk: Den låsbare titaniumadapteren til PD-kateter er beregnet på å feste peritonealkateterslangene til Baxter Minisett som brukes under peritonealdialysebehandling.

Kontraindikasjoner

Bruk ikke povidonjod til å koble Minisettet til Baxter Titaniumadapter ved kjente allergiske reaksjoner på jod. Bruk andre desinfiseringsmidler eller antiseptiske midler som ikke inneholder jod, hydrogenperoksid, alkohol eller blekemiddel.

Advarsler

Bruk aseptisk teknikk. Hvis noen del av væskebanen blir kontaminert, kan det føre til peritonitt.

Denne enheten er beregnet for engangstilkobling til pasientens PD-kateter. Enheten skal ikke brukes på nytt. Gjenbruk eller reprosessering av denne enheten kan føre til kontaminasjon av og skade på enhetens funksjon eller strukturelle integritet.

Det anbefales å overvåke skjoldbruskkjertelens funksjon hos pasienter med små fyllingsvolum av peritonealdialysevæske, typisk hos spedbarn og barn. Reduser jodeksponeringen så mye som mulig ved å tømme innholdet i bukhulen i tømmepose/-avløp før oppstart av neste fyllingssyklus, når det er klinisk mulig.

Skal ikke brukes hvis posen er skadet.

Hvis det oppstår kontaminasjon under innføring av adapteren, kan det føre til peritonitt. Adapteren skal føres inn i et sterilt kateter i henhold til prosedyren under.

Mange dialyseprodukter som er tilgjengelige fra andre produsenter, brukes med utstyr og forbruksmateriell fra Baxter Healthcare Corporation. Baxter har ingen kontroll over variasjoner, toleranser, mekanisk styrke eller eventuelle endringer i disse produktene. Baxter kan derfor ikke garantere at dialyseprodukter fra andre produsenter vil fungere tilfredsstillende ved bruk sammen med Baxters produkter.

Bruksanvisning

Bruk aseptisk teknikk

1. Lag et aseptisk arbeidsområde. Plasser adapteren i det aseptiske arbeidsområdet.
2. For generelle prosedyrer for klargjøring av kateter, les bruksanvisningen for kateteret.
3. Klem av kateteret.
4. Rengjør koblingen med povidonjod i 1 minutt, ved bruk av en steril gaskompress.
5. Dynk kateteradapteren og kateterslangen i povidonjodoppløsning i 5 minutter.
6. Fjern om nødvendig den brukte adapteren ved å klippe av kateteret med en steril saks rett under adapteren. Klipp av kateteret slik at det blir rette kanter, for enklere tilpasning.
7. Før kateteret inn i den smaleste enden på låsehylsen. Skyv hylsen oppover kateteret for å eksponere enden av kateteret.
8. Før kateteradapteren inn i kateteret. Kateteret skal rekke helt fram til den bredeste delen av adapteren. Etter innføringen inspiseres kateterslangen på innføringsstedet for å kontrollere at adapteren sitter helt fast, og at det ikke er sprekker eller revner i kateteret. Adapteren skal passe eksakt i kateteret, og hvis man trekker i adapteren, skal dette ikke føre til noen glidning av adapteren i kateteret.
9. Skyv hylsen tilbake ned over kateteret mot adapteren. Skru hylsen fast til adapteren så den sitter godt.
10. Dynk kateteret med adapteren i povidonjodoppløsning i nye 5 minutter.
11. Sett en Sterilbeskyttelse for PD-kateteradapter på adapteren, eller koble til MiniSett.
12. Fjern kateterklemmen.
13. Kast den brukte adapteren i samsvar med lokale retningslinjer for avfallshåndtering.

Kun til engangsbruk

Se bruksanvisningen

Pyrogenfri

Skal ikke brukes hvis emballasjen er skadet.

RT Oppbevares ved romtemperatur

Produsent

STERILE EO Sterilisert med etylenoksid

Προσαρμογέας Ασφαλείας από Τιτάνιο για Καθετήρα Περιτοναϊκής Κάθαρσης

gre

Περιγραφή

Ο προσαρμογέας αυτός είναι ένας προσαρμογέας θηλυκού συνδέσμου Luer lock διπλής στεγανοποίησης ο οποίος διαθέτει σύνδεσμο καθετήρα 2 τμημάτων που συνδυάζει εφαρμογή συμπίεσης/ακίδας. Ο προσαρμογέας χρησιμοποιείται για τη σύνδεση του καθετήρα περιτοναϊκής κάθαρσης σε συνδετική γραμμή διαλύματος με σύνδεσμο ασφαλείας. Ο προσαρμογέας αυτός είναι συμβατός με καθετήρες περιτοναϊκής κάθαρσης που διαθέτουν ονομαστικές διαστάσεις 2,6 mm εσωτ. διαμ. / 5 mm εξωτ. διαμ. και 3,5 mm εσωτ. διαμ. / 5,1 mm εξωτ. διαμ.

Στείρο, μη πυρετογόνο. Αποστειρωμένο με οξείδιο του αιθυλενίου.

Ενδείξεις χρήσης: Ο προσαρμογέας ασφαλείας από τιτάνιο για καθετήρα περιτοναϊκής κάθαρσης προορίζεται για την ασφάλιση της σωλήνωσης του καθετήρα περιτοναϊκής κάθαρσης στις συνδετικές γραμμές της Baxter που χρησιμοποιούνται στη διάρκεια της θεραπείας περιτοναϊκής κάθαρσης.

Αντενδείξεις

Μη χρησιμοποιείτε ιωδιούχο ποβιδόνη για σύνδεση των συνδετικών γραμμών στον προσαρμογέα τιτανίου της Baxter εάν υπάρχει γνωστό ιστορικό αλλεργικής αντίδρασης στο ιώδιο. Χρησιμοποιείτε άλλους απολυμαντικούς ή αντισηπτικούς παράγοντες που δεν περιέχουν ιώδιο, υπεροξείδιο του υδρογόνου, αλκοόλη ή λευκαντικό.

Προειδοποιήσεις

Χρησιμοποιήστε άσηπτη τεχνική. Η επιμόλυνση οποιουδήποτε τμήματος της διόδου υγρών ενδέχεται να έχει ως αποτέλεσμα την πρόκληση περιτονίτιδας.

Η συσκευή αυτή προορίζεται για εφάπαξ σύνδεση στον καθετήρα περιτοναϊκής κάθαρσης του ασθενούς. Μην επαναχρησιμοποιείτε αυτήν τη συσκευή. Η επαναχρησιμοποίηση ή επανεπεξεργασία αυτής της συσκευής μπορεί να οδηγήσει σε μόλυνση και υποβάθμιση της λειτουργίας της συσκευής ή της δομικής της ακεραιότητας.

Συνιστάται η παρακολούθηση της λειτουργίας του θυρεοειδή σε ασθενείς με μικρούς όγκους εισαγωγής διαλύματος περιτοναϊκής κάθαρσης, τυπικά σε βρέφη και παιδιά. Προκειμένου να ελαχιστοποιηθεί η έκθεση στο ιώδιο, πραγματοποιήστε εξαγωγή του περιεχομένου της περιτοναϊκής κοιλότητας στον υποδοχέα εξαγωγής πριν από την έναρξη του επόμενου κύκλου εισαγωγής, όποτε είναι κλινικά εφικτό.

Μην το χρησιμοποιείτε εάν ο θύλακας έχει υποστεί ζημιά.

Η επιμόλυνση κατά τη διάρκεια της εισαγωγής του προσαρμογέα ενδέχεται να έχει ως αποτέλεσμα την πρόκληση περιτονίτιδας. Ο προσαρμογέας πρέπει να εισάγεται σε στείρο καθετήρα, ακολουθώντας την παρακάτω διαδικασία.

Πολλά προϊόντα διαπίδυσης (κάθαρσης) άλλων παρασκευαστών χρησιμοποιούνται με εξοπλισμό ή αναλώσιμα της Baxter Healthcare Corporation. Η Baxter δεν είναι σε θέση να ελέγξει τη μεταβλητότητα, τις ανοχές και τη μηχανική αντοχή των εν λόγω προϊόντων ούτε τις τροποποιήσεις που ενδέχεται να γίνονται σε αυτά κατά καιρούς. Κατά συνέπεια, η Baxter δεν μπορεί να διασφαλίσει ότι τα προϊόντα κάθαρσης των άλλων παρασκευαστών θα λειτουργούν με ικανοποιητικό τρόπο όταν συνδεθούν με τα προϊόντα της.

Οδηγίες χρήσης

Χρησιμοποιήστε άσηπτη τεχνική

1. Δημιουργήστε άσηπτο πεδίο. Τοποθετήστε τον προσαρμογέα στο άσηπτο πεδίο.
2. Για τη γενική διαδικασία προετοιμασίας του καθετήρα, ανατρέχετε στις οδηγίες χρήσης του καθετήρα, όταν απαιτείται.
3. Σφίξτε τον καθετήρα.
4. Καθαρίστε σχολαστικά το σημείο σύνδεσης για 1 λεπτό με ιωδιούχο ποβιδόνη, χρησιμοποιώντας στείρα γάζα.
5. Εμβαπτίστε τον προσαρμογέα και τη σωλήνωση του καθετήρα σε διάλυμα ιωδιούχου ποβιδόνης για 5 λεπτά.
6. Όπου είναι εφαρμόσιμο, αφαιρέστε τον χρησιμοποιημένο προσαρμογέα κόβοντας τον καθετήρα με στείρο ψαλίδι, ακριβώς κάτω από τον προσαρμογέα. Κόψτε τον καθετήρα, ευθυγραμμίζοντας τα άκρα του για τη διευκόλυνση της στερέωσης.
7. Εισάγετε το μικρό βιδωτό άκρο της θήκης του προσαρμογέα ασφαλείας στον καθετήρα και τραβήξτε τη θήκη γλιστρώντας την πάνω στον καθετήρα, ώστε να μείνει ακάλυπτο το άκρο του καθετήρα.
8. Εισάγετε τον προσαρμογέα μέσα στον καθετήρα έως τον ώμο. Μετά την εισαγωγή, ελέγξτε τη σωλήνωση του καθετήρα στο σημείο εισαγωγής, ώστε να βεβαιωθείτε ότι ο προσαρμογέας έχει στερεωθεί πλήρως και ότι δεν υπάρχουν σχισμές ή ρωγμές στον καθετήρα. Ο προσαρμογέας πρέπει να εφαρμόζει επαρκώς μέσα στον καθετήρα και τυχόν τραβήγματα στον προσαρμογέα δεν πρέπει να προκαλούν ολίσθηση του καθετήρα.
9. Τραβήξτε τη θήκη γλιστρώντας την πάνω στον καθετήρα πίσω προς την κατεύθυνση του προσαρμογέα. Βιδώστε τη θήκη πάνω στον προσαρμογέα, έως ότου εφαρμόσει σταθερά.
10. Εμβαπτίστε τον καθετήρα μαζί με τον προσαρμογέα σε διάλυμα ιωδιούχου ποβιδόνης για ακόμη 5 λεπτά.
11. Πωματίστε τον προσαρμογέα με το πώμα ασφάλισης για προσαρμογέα καθετήρα περιτοναϊκής κάθαρσης ή συνδέστε τη συνδετική γραμμή.
12. Αφαιρέστε τον σφιγκτήρα του καθετήρα.
13. Απορρίψτε τον χρησιμοποιημένο προσαρμογέα σύμφωνα με τις τοπικές κατευθυντήριες οδηγίες απόρριψης αποβλήτων.

Μην επαναχρησιμοποιείτε

Συμβουλευθείτε τις οδηγίες χρήσης

Μη πυρετογόνο

Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά.

RT Φυλάσσετε σε θερμοκρασία δωματίου

Κατασκευαστής

STERILE EO Αποστειρωμένο με οξείδιο του αιθυλενίου

Baxter Healthcare SA
8010 Zurich, Switzerland

Baxter Healthcare Corporation
Deerfield IL 60015, USA

Made in Ireland

CE 0123

Rev. 2015-05-01
SW-30-01-057

TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Baxter Healthcare SA
Thurgauerstrasse 130
8152 GLATTPARK (OPFIKON)
SWITZERLAND

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
56740	713293693	+393476784153 anna.morandini@tuvsud.com		2024-02-06	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 056740 0049 Rev. 00

Reference: 713293693

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: **CH-MF-000026124**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC

(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 056740 0049 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
06.02.2024

TÜV SÜD Product Service GmbH Medical and Health Services	TÜV SÜD Product Service GmbH Medical and Health Services
Conformity Assessment Responsible (CARE)	Application Reviewer

Product Service

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HomeChoice Automated PD Set with Cassette and 8-Prong Luers **HomeChoice Automated PD Set with Cassette and 4-Prong Luers** **HomeChoice Low Recirculation Volume APD Set with Cassette** **00854120000000000000042J2**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: Current MDD code is R5C4479T and it will be substituted by R5C4479E and R5C4479	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Calcium Line – CA250 **00854120000000000000176JQ**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
MiniCap Extended Life PD Transfer Set with Twist Clamp **MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Short** **MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Long** **00854120000000000000177JS**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Povidone-Iodine MiniCap **MiniCap with Povidone-Iodine** **00854120000000000000178JU**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		Evidence #1; CA# Evidence #2; CA#
Flexicap Disconnect Cap with Povidone-Iodine Solution **00854120000000000000179JW**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Connection Shield Sys II with Povidone **Connection Shield Sys II with Povidone-Iodine Solution** **00854120000000000000180JF**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
3,65 m Extension Set with Luer-lock Connector **00854120000000000000193JQ**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
5 Prong Manifold Set (with Luer Connectors) **00854120000000000000205J6**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		Evidence #1; CA# Evidence #2; CA#
Locking Titanium PD Catheter Adapter **0085412GMDN000000000615XH**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 062680 0149, NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/02/06	713293693	Initial issue

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Legal Manufacturer Name: Baxter Healthcare SA

Legal Manufacturer Address: 8010 Zürich, Switzerland

Legal Manufacturer Single Registration Number (SRN): CH-MF-000026124

Authorised Representative Name (if applicable): Baxter Deutschland GmbH

Authorised Representative Address: Edisonstrasse 4 85716 Unterschleissheim, Germany

Authorised Representative Single Registration Number (SRN): DE-AR-000010308

Notified Body Name and Address:

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany

Notified Body Identification Number: 0123

MDD Certificate Number: G1 062680 0149 Rev. 00

Original expiry date as indicated on the MDD Certificate prior to the extension of the validity: 26 May 2024

End date of extended validity/transition period [1]: 31 December 2028

[1] according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).

+++ We, as the legal manufacturer declare under our sole responsibility:

- for the above listed **MDD Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions: +++

This declaration is made on the following basis:

1. The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.
2. The device(s) continue to comply with Directive 93/42/EEC (MDD)
3. The device does not undergo a significant change in the design and intended purpose from 26 May 2021.
4. The device(s) do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
5. Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

6. A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) is put in place by the manufacturer no later than 26 May 2024.

7. A formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made to the notified body for the device(s) listed on this declaration or has been made in respect of a device intended to substitute a device listed on this declaration, no later than 26 May 2024 and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) no later than 26 September 2024.

Product/Trade Name and Product Code or REF. number: *Refer to Appendix A*

Device MDR Risk Class: IIa and IIb

Authorised Signatory:	
Name and Title:	
Function	QMR and PRRC
Place of Issue:	Zürich, Switzerland
Date of Issue:	
Signature:	

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix A: List of medical devices from MDD DoC or PCL

Product Code or REF number	Product or Trade Name
1PC4466T	Povidone-Iodine MiniCap
BEPC4129	Locking Titanium PD Catheter Adapter
BEPC4456	Flexicap Disconnect Cap with Povidone-Iodine Solution
BEPC4466	MiniCap with Povidone-Iodine
EVPC4456	Flexicap Disconnect Cap with Povidone-Iodine Solution
HJPC4211	Connection Shield Sys II with Povidone
PPC4129	Locking Titanium PD Catheter Adapter
R5C4427	5 Prong Manifold Set (with Luer Connectors)
R5C4478	HomeChoice Automated PD Set with Cassette and 8-Prong Luers
R5C4479	HomeChoice Automated PD Set with Cassette and 4-Prong Luers
R5C4479E	HomeChoice Automated PD Set with Cassette and 4-Prong Luers
R5C4480F	3,65 m Extension Set with Luer-lock Connector
R5C4482	MiniCap Extended Life PD Transfer Set with Twist Clamp
R5C4482E	MiniCap Extended Life PD Transfer Set with Twist Clamp
5C4482S	MiniCap Extended Life PD Transfer Set with Twist Clamp
R5C4483	MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Short
R5C4484	MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Long
R5C8303	HomeChoice Low Recirculation Volume APD Set with Cassette
SPC4129	Locking Titanium PD Catheter Adapter
SPC4211	Connection Shield Sys II with Povidone-Iodine Solution
SPC4456	Flexicap Disconnect Cap with Povidone-Iodine Solution
SPC4466	MiniCap with Povidone-Iodine
955687	Calcium Line – CA250
955688	Calcium Line – CA250
R5C4479T	HomeChoice Automated PD Set with Cassette and 4-Prong Luers

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix B: Relationship Between MDD and MDR Codes

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
R5C4479T	HomeChoice Automated PD Set with Cassette and 4-Prong Luers	R5C4479E substitute*	HomeChoice Automated PD Set with Cassette and 4-Prong Luers	TÜV SÜD	Baxter Healthcare SA

[2] Refers to procedure GQP-09-27 for a definition of substitute device

*R5C4479E is part of the pre-application EC-R-005-22, R5C4479T is not part of the pre-application EC-R-005-22 so once the MDD extension period ends R5C4479T will be substituted by R5C4479E.