

SUPER SAFE | SUSTAINABLE | SMART



SAFER SYRINGE



SAFER STING



Roncadelle Operations 1936

Prevenzione del rischio di lesione
Prevention of injury prevention
Prevention der Verletzung
Удаление экстракорпусальной иглы
Removal of the extracorporeal needle
Removal der Nadel
Prevenção de lesões por punção
Prevention of injury prevention
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ENGLISH

PRODUCT NAME
SafeR® Syringe, safety syringe (hereafter SafeR® syringe)
SafeR® Sting, retractable safety needle (hereafter SafeR® needles)
SIZES
Standard gauge availability: 20G, 21G, 22G, 23G, 25G, 26G, 27G.
An 18G blunt fill needle is provided separately. SafeR® needles is provided separately. Compatibility between SafeR® syringe and SafeR® needle is guaranteed and easy to use.
INTENDED USE
SafeR® is an automatically Retractable Safety Syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids and the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID)and subcutaneous (SC)). The syringe, once assembled with its needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in the prevention of possible infections due to needstick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand.

INSTRUCTION FOR USE
Follow the institution's protocol for applying the aseptic technique (or follow the indication of medical personnel) and skin area preparation. Wash your hands, arrange a suitable, clean place (table) with medical waste, syringe and alcohol swabs, sharp container.
Peel off the packages to access both the desired SafeR® syringe and desired SafeR® needles. Attach the SafeR® blunt fill needle to the SafeR® syringe with a clockwise twist and perform medication preparation and drug aspiration. Then, once the syringe is filled with the desired quantity of medicine, remove the blunt fill needle and dispose of it in a sharps container.
Attach the SafeR® Needle for injection to the SafeR® syringe by clicking the plunger button until the retraction mechanism is activated. The needle will be automatically retracted inside the barrel and a haptic feeling will be perceived as well as a "click" sound.
Do not remove the needle connector after use. Dispose of the syringe in the sharps container.

FEATURES
Biocompatible, Sterile, Pyrogen Free. Safety feature operated with one hand.
Harmless to patient and user once needle is retracted. The needle can be retracted directly from the body.

• End users should be familiar with instruction for use and be trained in the administration of medication and injections.
• Do not use if single unit package is damaged or needle cap is detached.
• The syringes and needles are sterile (EO sterilization) until removed from their protective packaging. They are for single use only.
• Do not push the leading edge of the plunger gasket where the O-line before injection.
• To minimize the likelihood of leakage, inject slowly and select the needle gauge appropriate to the medication viscosity.
• To reduce the likelihood of leakage when injecting high-viscosity fluids, select the appropriate gauge size before injection.
• The needle retrieval mechanism can only be activated when the medication or fluid is fully injected.
• Do not push the syringe further inside the body while activating the retracting mechanism.
• If the needle is not automatically retracted, dispose of the syringe in the sharps container without recapping the needle.
• Discard of the syringe immediately after use without any further utilization.

WARNING:
• SafeR® retractable needle is designed for use with SafeR® syringes only.
• Syringe Re-use could lead to infection or transmission of diseases: do not try to re-use the device.
• Do not use on patient having a body weight lower than 3 kg.
• Do not try to use needles other than SafeR® retractable needles with SafeR® Syringe.
• Do not use this product to draw blood or for endovenous punctures.
• SafeR® is a single use device: Do not re-sterilize.
• Blunt fill needle is designed only for drug preparation and it is not intended to come in contact with the human body. DO NOT FOR MEDICATION INJECTION.
• Report any device malfunction, deterioration in device performance, inadequate instructions, or inadequate labeling to the manufacturer and competent authority, as if not reported, this may result in death or serious injury that may lead to death or serious deterioration in state of health.

PRECAUTIONS
• End users should be familiar with instruction for use and be trained in the administration of medication and injections.

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ITALIANO
NOME DEL PRODOTTO
SafeR®Syringe, siringa di sicurezza, (di seguito Siringa SafeR®) SafeR® Sting, ago di sicurezza retrattile (di seguito ago SafeR®)
Capacità della siringa: Siringa di sicurezza da 1ml, 2ml, 2,25ml, 3ml, 5ml.
Dimensioni ago: 20G, 21G, 22G, 23G, 25G, 26G, 27G.
Un ago smusso di riempimento 18G è fornito separatamente. L'ago SafeR® è fornito separatamente. La compatibilità tra l'ago SafeR® e l'ago SafeR® è garantita per ogni dimensionell'ago.
PREVENZIONE DEL RISCHIO DI LESIONE
Prevention of injury prevention
Prevention der Verletzung
Удаление экстракорпусальной иглы
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INDICAZIONI D'USO
SafeR® è una siringa di sicurezza automaticamente retrattile, progettata per consentire un metodo sicuro, accurato e affidabile per l'aspirazione dei fluidi e per l'iniezione di fluidi immediatamente dopo il riempimento. È destinata ad essere utilizzata per somministrazione di farmaci (intramuscolare (IM), intradermica (ID) e sottocutanea (SC)). La siringa, una volta assemblata con il suo ago, incorpora un meccanismo di sicurezza passiva che ritrae e contiene l'ago contaminato dopo l'uso, aiutando nella prevenzione di possibili infezioni dovute a lesioni da aghi e riutilizzo della siringa. La retrazione dell'ago viene attivata dall'utilizzatore della siringa con un solo dito.
ISTRUZIONI PER L'USO
Seguire il protocollo istituzionale per l'applicazione della tecnica asettica (o seguire l'indicazione del personale medico) e la preparazione dell'area cutanea. Lavarsi le mani e disporre un'area adatta e pulita (tavolo) con bottiglia di medicinale, siringa, tamponi imbevuti di alcool, contenitore per taglietti.
Aprire le confezioni per estrarre sia la siringa SafeR® desiderata che il suo ago. Incorporare l'ago smusso di riempimento SafeR® alla siringa SafeR® con una rotazione in senso orario ed eseguire la preparazione del farmaco e l'aspirazione del farmaco. Quindi, una volta riempita la siringa con la quantità desiderata di medicinale, rimuovere l'ago di ricambio e smaltirlo in un contenitore per taglietti.
Collegare l'ago SafeR® per l'iniezione alla siringa SafeR® con una rotazione in senso orario.
Estrarre il cappuccio dall'ago ed espellere le bolle d'aria. Iniettare il farmaco nella vena sottocutanea o nel muscolo sotto l'indicazione del personale medico. Assicurarsi che tutto il farmaco sia iniettato.
Continuare a premere il pulsante dello stantuffo fino a quando il meccanismo di retrazione è viene attivato. La siringa e l'ago saranno automaticamente ritratti all'interno della siringa e verrà percorsa una sensazione tattile e un tipico suono di "click".
Non rimuovere il connettore dell'ago dopo l'uso. Smaltire sempre il contenitore per oggetti taglietti.

CARATTERISTICHE
Biocompatibile, sterile, apirogeno.
Funzione di sicurezza azionata con una sola mano. Innoceo per il paziente e l'utente una volta che l'ago viene retrainato.
L'ago è automaticamente ritratto direttamente dal corpo.
PRECAUZIONI
• Gli utenti finali devono avere familiarità con le istruzioni operative L'uso ed essere addestrati nella somministrazione di farmaci e iniezioni.
• Non usare se la confezione di una singola unità è danneggiata o il cappuccio dell'ago è staccato.
• Le siringhe e gli aghi sono sterili (sterilizzazione EO) fino a quando non vengono rimossi dalla loro confezione protettiva. Sono esclusivamente monouso.
• Non spingere il bordo anteriore della guaina o dello stantuffo sulla linea dello 0 prima dell'iniezione.
• Per ridurre al minimo la probabilità di perdita, inniettare lentamente e selezionare l'ago del diametro appropriato ad alta viscosità, selezionare la dimensione del diametro dell'ago appropriata prima dell'iniezione.
• Il meccanismo di retrazione dell'ago può essere attivato solo quando il farmaco o il fluido è stato completamente iniettato.
• Non spingere ulteriormente la siringa all'interno del corpo mentre si attiva il meccanismo di retrazione.
• Se l'ago non viene ritratto automaticamente, smaltire

la siringa nel contenitore per taglietti senza richiudere l'ago.
• Smaltire la siringa immediatamente dopo l'uso senza ulteriore manipolazione.
• La rieducazione del paziente sui rischi è fondamentale. Evitare l'uso ripetuto del dispositivo.
• Il suo uso può essere vietato se il paziente ha una malattia che impedisca l'uso di un prodotto iniettabile.
• La siringa è adatta per il riempimento e per l'iniezione in senso orario ed eseguire la preparazione del farmaco e l'aspirazione del farmaco. Quindi, una volta riempita la siringa con la quantità desiderata di medicinale, rimuovere l'ago di ricambio e smaltirlo in un contenitore per taglietti.
Drehen Sie die Verpackung, um sowohl die gewünschte SafeR®-Spritze als auch die gewünschte(S) SafeR®-Nadel(n) zu entnehmen. Drehen Sie die stumpfe SafeR®-Füllnadel im Uhrzeigersinn auf die gewünschte SafeR®-Nadel(n) zu. Bereiten Sie die Injektionsstelle vor. Waschen Sie Ihre Hände, und bereiten Sie einen geeigneten sauberen Arbeitsplatz (Tisch) mit Arzneimitteln, Spritzen, Scharfbehälter, Alkoholtupfer und einem Behälter für scharfe Gegenstände vor.
Nehmen Sie die Spritze mit und saugen Sie dieses Exemplar.
Füllen Sie die Spritze mit der gewünschten Menge des Medikaments befüllt wurde, entfernen Sie die stumpfe Füllnadel, und entsorgen Sie diese in einem Behälter für scharfe Gegenstände.
Drehen Sie die SafeR®-Injektionsnadel im Uhrzeigersinn auf die SafeR®-Spritze.
Entfernen Sie die Nadelkappe von der Nadel, und lassen Sie diese in einem Behälter für scharfe Gegenstände. Umgefahren Sie die Patienten und Benutzer, sobald die Nadel zurückgezogen wurde. Die Nadel kann direkt aus dem Körper zurückgezogen werden.
Nicht versuchen, die Nadel nach dem Gebrauch zu re-sterilisieren.
Die Injektionsnadeln sind für den Einmalgebrauch vorgesehen.
Das Risiko des Auslaufens zu minimieren, injizieren Sie langsam, und wählen Sie die Nadelstärke anhand der Viskosität des Medikaments.
Um beim Injizieren von hochviskosen Flüssigkeiten das Risiko von Leckagen zu verringern, wählen Sie vor dem Injizieren die geeignete Größe aus.
Der Rückführmechanismus der Nadel kann erst dann reaktiviert werden, wenn der Medikation oder die Flüssigkeit vollständig injiziert wurde.
Drücken Sie die Spritze nicht weiter in den Körper, wenn Sie den Rückführmechanismus aktivieren.
Nicht versuchen, die Nadel mit dem Finger zurück zu ziehen, sondern Sie in den Behälter für scharfe Gegenstände zu entsorgen.
Drücken Sie die Spritze im Behälter für scharfe Gegenstände, ohne die Nadelkappe wieder anzubringen.
Entsorgen Sie die Spritze unverändert unmittelbar nach der Verwendung.

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• To minimize the likelihood of leakage, inject slowly and select the needle gauge appropriate to the medication viscosity.
• To reduce the likelihood of leakage when injecting high-viscosity fluids, select the appropriate gauge size before injection.
• The needle retrieval mechanism can only be activated when the medication or fluid is fully injected.
• Do not push the syringe further inside the body while activating the retracting mechanism.
• If the needle is not automatically retracted, dispose of the syringe in the sharps container without recapping the needle.
• Discard of the syringe immediately after use without any further utilization.

FRANÇAIS
NOM DU PRODUIT
SafeR®Syringe, seringue de sécurité (ci-après seringue SafeR®) SafeR® Sting, aiguille de sécurité retractable (ci-après aiguille SafeR®)
Capacités des seringues : Seringue de sécurité 1 ml, 2 ml, 2,25 ml, 3 ml, 5 ml.
Grilles : aiguilles de jauge d'aiguille : 20 G, 21 G, 22 G, 23 G, 25 G, 26 G, 27 G.
Un aiguille de remplissage émoussée 18 G est fournie séparément.
L'aiguille SafeR® est fournie séparément. La compatibilité entre l'aiguille SafeR® et l'aiguille SafeR® est garantie pour chaque taille d'aiguille.
UTILISATION PRÉVUE
SafeR® est une seringue de sécurité rétractable automatique, destinée à proposer un méthode sûre, précise et fiable pour la aspiration de fluides et à l'injection de fluides immédiatement après le remplissage. Elle est destinée à être utilisée pour l'administration de médicaments (par voie intramusculaire (IM), intradermique (ID) et sous-cutanée (SC)). La seringue, une fois assemblée avec son aiguille, intègre un mécanisme de sécurité passive qui rétracte et contient l'aiguille contaminée après utilisation, contribuant ainsi à la prévention d'éventuelles infections transmises par le patient. L'aiguille est activée après l'injection de médicaments, de produits pharmaceutiques ou de solutions. Elle est activée à l'aide d'une simple manipulation.
SUIVEZ LE PROTOCOLE D'ÉTABLISSEMENT pour la technique aseptique (ou suivez les indications du personnel médical) et la préparation de la zone cutanée. Lavez les mains, préparez un espace approprié et propre (table) avec le flacon de médicaments, la seringue, les tampons d'alcool et le récipient pour objets tranchants.
Décollez les emballages pour extraire la seringue SafeR® et l'aiguille SafeR®. Préparez l'aiguille de remplissage émoussée SafeR® à la seringue SafeR® en la faisant tourner dans le sens des aiguilles d'une montre et procédez à la préparation du médicament et à l'aspiration du médicament.
Retirez l'aiguille de remplissage émoussée SafeR® de la seringue SafeR® en la faisant tourner dans le sens des aiguilles d'une montre.
Retirez le capuchon de l'aiguille et expulsez les bulles d'air. Injecter les médicaments, selon le protocole médical établi ou les indications du personnel médical. S'assurer que tout médicament est injecté.
Continuer à appuyer sur le bouton-poussoir jusqu'à l'activation du mécanisme de récupération. L'aiguille sera automatiquement rétractée à l'intérieur du cylindre et une sensation haptique sera perçue, en même temps qu'un son de "clac".
Ne retirez pas le connecteur de l'aiguille après utilisation. Injecter la seringue dans le conteneur pour objets tranchants.

PRECAUTIONS
• Les utilisateurs finaux doivent être familiarisés avec les instructions de utilisation et possuir formation en administration de médicaments et injections.
• Ne pas utiliser se une emballage de une unidade estiver danificada ou se a tampa da agulha estiver solta.
• As seringas e agulhas são fornecidas esterilizadas (esterilização EO) hasta que se abra a tampa de sua embalagem deproteção. São de uso único.
• Não empurrar o bordo condutor da junta do êmbolo sobre a linha 0 antes da injeção.
• Para minimizar a probabilidade de derrame, injetar lentamente o medicamento no cilindro.
• O mecanismo de retracção da agulha só pode ser ativado quando a medicação o fluido forem totalmente injetados.
• Não empurre a seringa mais para dentro do corpo em direção ao recipiente de resíduos do que o próprio êmbolo.
• Se a agulha não for retratada automaticamente, deposite a seringa no contendor de objetos cortantes sem voltar a apalhar a agulha.
• Deitar fora o conector da agulha imediatamente após a sua utilização sem qualquer outra manipulação.
ADVERTÊNCIAS
• A agulha retratável SafeR® foi concebida para ser utilizada apenas com seringas SafeR®.
• A reutilização da seringa pode levar à infeção ou transmissão de doenças: não tente reutilizar o dispositivo.
• O dispositivo não deve ser usado em pacientes com peso corpóreo inferior a 3 kg.
• Não tente usar agulhas diferentes das agulhas retratáveis SafeR®.
• Não utilize este produto para colher sangue ou para punções endovenosas.
• SafeR® é um dispositivo de uso único: Não re-esterilizar.
• A agulha de enchimento rômbo foi concebida apenas para a preparação de fármacos e não se destina a entrar em contacto com o corpo humano. NÃO A UTILIZAR PARA INJEÇÃO DE MEDICAMENTOS.
• Comunique ao fabricante e à autoridade competente que qualquer defeito de segurança incorreto do dispositivo, deterioração do seu desempenho, instruções inadequadas, ou rotulagem inadequada que resulte em morte ou ferimentos graves, ou possa levar à morte ou deterioração grave do seu estado de saúde caso se repita.

PRECAUTIONS
• Users should be familiar with instruction for use and be trained in the administration of medication and injections.
• Do not use if single unit package is damaged or needle cap is detached.
• The syringes and needles are sterile (EO sterilization) until removed from their protective packaging. They are for single use only.
• Do not push the leading edge of the plunger gasket where the O-line before injection.
• To minimize the likelihood of leakage, inject slowly and select the needle gauge appropriate to the medication viscosity.
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• The needle retrieval mechanism can only be activated when the medication or fluid is fully injected.
• Do not push the syringe further inside the body while activating the retracting mechanism.
• If the needle is not automatically retracted, dispose of the syringe in the sharps container without recapping the needle.
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Tailles des seringues : Seringue de sécurité 1 ml, 2 ml, 2,25 ml, 3 ml, 5 ml.
Grilles : aiguilles de la jauge d'aiguille : 20 G, 21 G, 22 G, 23 G, 25 G, 26 G, 27 G.
Une aiguille de remplissage émoussée 18 G est fournie séparément.
L'aiguille SafeR® est fournie séparément. La compatibilité entre l'aiguille SafeR® et l'aiguille SafeR® est garantie pour chaque taille d'aiguille.
UTILISATION PRÉVUE
SafeR® est une seringue de sécurité rétractable automatique, destinée à proposer un méthode sûre, précise et fiable pour la aspiration de fluides et à l'injection de fluides immédiatement après le remplissage. Elle est destinée à être utilisée pour l'administration de médicaments (par voie intramusculaire (IM), intradermique (ID) et sous-cutanée (SC)). La seringue, une fois assemblée avec son aiguille, intègre un mécanisme de sécurité passive qui rétracte et contient l'aiguille contaminée après utilisation, contribuant ainsi à la prévention d'éventuelles infections transmises par le patient. L'aiguille est activée après l'injection de médicaments, de produits pharmaceutiques ou de solutions. Elle est activée à l'aide d'une simple manipulation.
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• As seringas e agulhas são fornecidas esterilizadas (esterilização EO) hasta que se abra a tampa de sua embalagem deproteção. São de uso único.
• Não empurrar o bordo condutor da junta do êmbolo sobre a linha 0 antes da injeção.
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• Não empurre a seringa mais para dentro do corpo em direção ao recipiente de resíduos do que o próprio êmbolo.
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L'aiguille SafeR® est fournie séparément. La compatibilité entre l'aiguille SafeR® et l'aiguille SafeR® est garantie pour chaque taille d'aiguille.
UTILISATION PRÉVUE
SafeR® est une seringue de sécurité rétractable automatique, destinée à proposer un méthode sûre, précise et fiable pour la aspiration de fluides et à l'injection de fluides immédiatement après le remplissage. Elle est destinée à être utilisée pour l'administration de médicaments (par voie intramusculaire (IM), intradermique (ID) et sous-cutanée (SC)). La seringue, une fois assemblée avec son aiguille, intègre un mécanisme de sécurité passive qui rétracte et contient l'aiguille contaminée après utilisation, contribuant ainsi à la prévention d'éventuelles infections transmises par le patient. L'aiguille est activée après l'injection de médicaments, de produits pharmaceutiques ou de solutions. Elle est activée à l'aide d'une simple manipulation.
SUIVEZ LE PROTOCOLE D'ÉTABLISSEMENT pour la technique aseptique (ou suivez les indications du personnel médical) et la préparation de la zone cutanée. Lavez les mains, préparez un espace approprié et propre (table) avec le flacon de médicaments, la seringue, les tampons d'alcool et le récipient pour objets tranchants.
Décollez les emballages pour extraire la seringue SafeR® et l'aiguille SafeR®. Préparez l'aiguille de remplissage émoussée SafeR® à la seringue SafeR® en la faisant tourner dans le sens des aiguilles d'une montre et procédez à la préparation du médicament et à l'aspiration du médicament.
Retirez l'aiguille de remplissage émoussée SafeR® de la seringue SafeR® en la faisant tourner dans le sens des aiguilles d'une montre.
Retirez le capuchon de l'aiguille et expulsez les bulles d'air. Injecter les médicaments, selon le protocole médical établi ou les indications du personnel médical. S'assurer que tout médicament est injecté.
Continuer à appuyer sur le bouton-poussoir jusqu'à l'activation du mécanisme de récupération. L'aiguille sera automatiquement rétractée à l'intérieur du cylindre et une sensation haptique sera perçue, en même temps qu'un son de "clac".
Ne retirez pas le connecteur de l'aiguille après utilisation. Injecter la seringue dans le conteneur pour objets tranchants.

PRECAUTIONS
• Les utilisateurs finaux doivent être familiarisés avec les instructions de utilisation et possuir formation en administration de médicaments et injections.
• Ne pas utiliser se une emballage de une unidade estiver danificada ou se a tampa da agulha estiver solta.
• As seringas e agulhas são fornecidas esterilizadas (esterilização EO) hasta que se abra a tampa de sua embalagem deproteção. São de uso único.
• Não empurrar o bordo condutor da junta do êmbolo sobre a linha 0 antes da injeção.
• Para minimizar a probabilidade de derrame, injetar lentamente o medicamento no cilindro.
• O mecanismo de retracção da agulha só pode ser ativado quando a medicação o fluido forem totalmente injetados.
• Não empurre a seringa mais para dentro do corpo em direção ao recipiente de resíduos do que o próprio êmbolo.
• Se a agulha não for retratada automaticamente, deposite a seringa no contendor de objetos cortantes sem voltar a apalhar a agulha.
• Deitar fora o conector da agulha imediatamente após a sua utilização sem qualquer outra manipulação.
ADVERTÊNCIAS
• A agulha retratável SafeR® foi concebida para ser utilizada apenas com seringas SafeR®.
• A reutilização da seringa pode levar à infeção ou transmissão de doenças: não tente reutilizar o dispositivo.
• O dispositivo não deve ser usado em pacientes com peso corpóreo inferior a 3 kg.
• Não tente usar agulhas diferentes das agulhas retratáveis SafeR®.
• Não utilize este produto para colher sangue ou para punções endovenosas.
• SafeR® é um dispositivo de uso único: Não re-esterilizar.
• A agulha de enchimento rômbo foi concebida apenas para a preparação de fármacos e não se destina a entrar em contacto com o corpo humano. NÃO A UTILIZAR PARA INJEÇÃO DE MEDICAMENTOS.
• Comunique ao fabricante e à autoridade competente que qualquer defeito de segurança incorreto do dispositivo, deterioração do seu desempenho, instruções inadequadas, ou rotulagem inadequada que resulte em morte ou ferimentos graves, ou possa levar à morte ou deterioração grave do seu estado de saúde caso se repita.

PRECAUTIONS
• Users should be familiar with instruction for use and be trained in the administration of medication and injections.
• Do not use if single unit package is damaged or needle cap is detached.
• The syringes and needles are sterile (EO sterilization) until removed from their protective packaging. They are for single use only.
• Do not push the leading edge of the plunger gasket where the O-line before injection.
• To minimize the likelihood of leakage, inject slowly and select the needle gauge appropriate to the medication viscosity.
• To reduce the likelihood of leakage when injecting high-viscosity fluids, select the appropriate gauge size before injection.
• The needle retrieval mechanism can only be activated when the medication or fluid is fully injected.
• Do not push the syringe further inside the body while activating the retracting mechanism.
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