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Instructions For Use

**Návod k použití • Gebrauchsanweisung • Instrucciones de uso
Mode d'emploi • Οδηγίες χρήσης • Istruzioni per l'uso
Gebruiksaanwijzing • Instruksjoner for bruk • Instrukcja użycia
Instruções de uso • Användningsinstruktioner**

Disposable Veress Needle

DE	Einweg-Veress-Nadel
ES	Aguja de Veress desechable
FR	Aiguille de Veress jetable
IT	Ago di Veress monouso
NL	Wegwerpbare Veress-naald
NO	Engangs Veress-nål
PT	Agulha de Veress descartável
SE	Veress-nål för engångsbruk

Indications / Intended use

Fairmont's Disposable Veress Needle is intended for use in minimally invasive surgical procedures, predominantly abdominal laparoscopic techniques. It is used to introduce or remove gas from the peritoneal cavity as a therapeutic or surgical/radiological procedural method. It is often inserted into the peritoneal cavity for the purpose of insufflation (e.g., with CO₂) to establish pneumoperitoneum prior to abdominal endoscopy.

Instructions For Use

1. Peel open pouch and remove product using standard aseptic techniques.
2. Prior to insertion, inspect the Veress Needle to ensure that the cannula moves freely over of the blunt obturator with minimal pressure applied to the device.
3. Insert the Veress Needle.
4. It is recommended to perform various checks to ensure that the Veress Needle is in the abdominal cavity ensuring red indicator is **not** visible on the safety window.
5. Once correct placement is ascertained, inflate to desired pressure.
6. Once insufflation is complete and the desired abdominal pressure is accomplished, remove the Veress Needle and proceed with laparoscopic procedure.

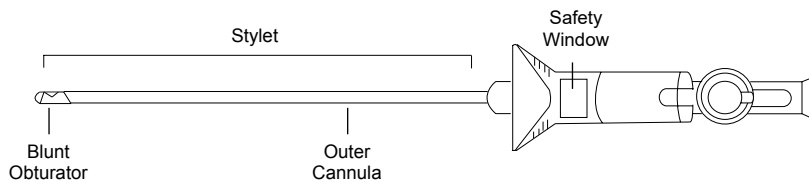
Precautions

- Single use only, do not re-use, re-process or re-sterilise.
- Suitably trained healthcare personnel may only use this device.
- Do not use if the stylet does not return over the blunt end when pressure on the stylet is released.
- Do not use the Veress Needle if the stylet is not functioning properly.
- This device is sterile (ETO). Please note, this IFU pertains to sterile devices sold by Fairmont Medical. If the device has code "DVNxxxNS" please refer to 3rd party manufacturer for sterility specifications.
- This device must be disposed of in accordance with local environmental laws and regulations

Materials

PVC, Acrylic, Natural TPR, stainless steel.

All components and packaging are latex and Phthalate-free PVC.



Any serious incidents that occur in relation to the device should be reported to the manufacturer and the competent authority of the Member State of the patient and/or user.

Indikationen (Verwendungszweck)

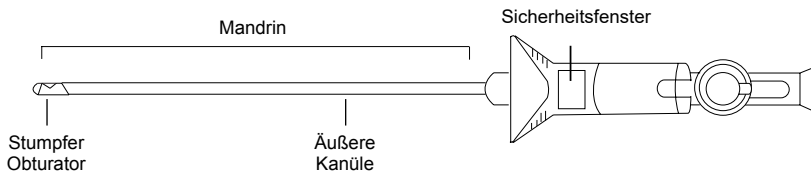
Gebrauchsanweisung

1. Öffnen Sie den Beutel und entnehmen Sie das Produkt mit aseptischen Standardtechniken.
2. Vor dem Einsetzen die Veress-Nadel prüfen, um sicherzustellen, dass sich die Kanüle mit minimalem Druck auf das Gerät frei über den stumpfen Obturator bewegt.
3. Die Veress-Nadel einsetzen.
4. Es wird empfohlen, verschiedene Kontrollen durchzuführen, um sicherzustellen, dass sich die Veress-Nadel in der Bauchhöhle befindet, sicherzustellen, dass die rote Linie auf dem Sicherheitsfenster **nicht** sichtbar ist.
5. Sobald die korrekte Platzierung festgestellt ist, auf den gewünschten Druck aufpumpen.
6. Wenn die Insufflation abgeschlossen ist und der gewünschte Abdominaldruck erreicht ist, entfernen Sie die Veress-Nadel und fahren Sie mit dem laparoskopischen Verfahren fort.

Vorsichtsmaßnahmen

Werkstoffe

Alle Komponenten und Verpackungen sind latex- und phthalatfrei.



Indicaciones (Uso previsto)

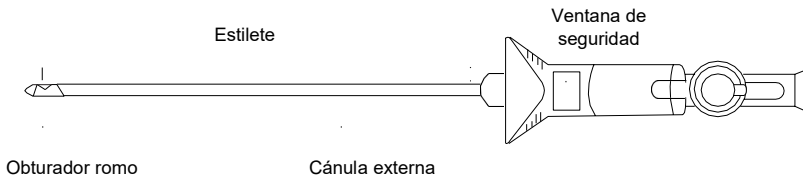
Precauciones

Instrucciones de uso

1. Abra el envoltorio y retire el producto usando técnicas asépticas habitual.
2. Antes de la inserción, examine la aguja de Veress para asegurarse de que la cánula se desplace libremente sobre el obturador romo al aplicar una presión mínima sobre el dispositivo.
3. Introduzca la aguja de Veress.
4. Se recomienda realizar varias comprobaciones para asegurarse de que la aguja de Veress está en la cavidad abdominal, verificando que la línea roja **no** sea visible en la ventana de seguridad.
5. Una vez que se haya comprobado la colocación correcta de la aguja, infle hasta la presión deseada.
6. Cuando finalice el insuflado y se haya alcanzado la presión abdominal deseada, retire la aguja de Veress y comience la intervención laparoscópica.

Materiales

Todos los componentes y envases están libres de ftalatos y látex.



Indications (Utilisation prévue)

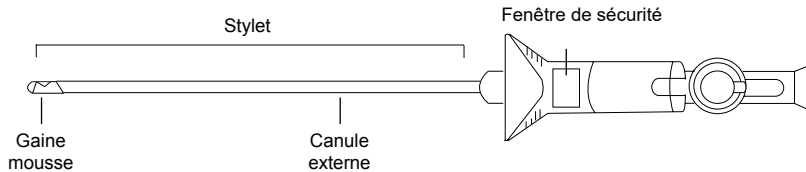
Instructions d'utilisation

1. Ouvrir le sachet et retirer le produit en respectant les techniques d'asepsie standards.
2. Avant son insertion, inspecter l'aiguille de Veress pour s'assurer que la canule sort librement de la gaine mousse de protection avec une pression minimale appliquée à l'appareil.
3. Insérer l'aiguille de Veress.
4. Il est recommandé d'effectuer divers contrôles pour s'assurer que l'aiguille de Veress se trouve dans la cavité abdominale, et pour s'assurer que la ligne rouge n'est pas visible sur la fenêtre de sécurité.
5. Une fois que le placement correct est établi, gonfler à la pression désirée.
6. Une fois l'insufflation terminée et la pression abdominale désirée atteinte, retirer l'aiguille de Veress et procéder à la procédure laparoscopique.

Précautions à prendre

Matériaux

Tous les composants et emballages sont exempts de latex et de phtalates.



Indicazioni (uso previsto)

L'ago di Veress monouso è un dispositivo sterile monouso con un meccanismo a mandrino smussato incorporato caricato a molla. Si utilizza per creare il pneumoperitoneo prima dell'inserimento del trocar e della cannula nelle procedure laparoscopiche. L'ago di Veress monouso è attualmente disponibile in tre diverse lunghezze: 120 mm, 150 mm e 200 mm. L'ago trova applicazione nell'ambito della laparoscopia ginecologica e di altre procedure laparoscopiche.

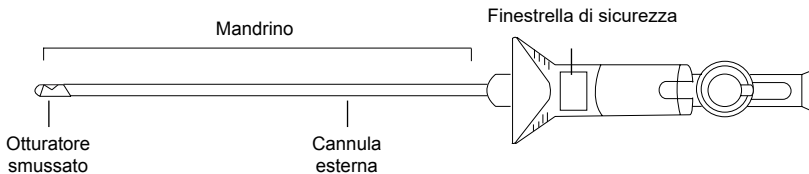
Istruzioni per l'uso

1. Aprire la busta e rimuovere il prodotto utilizzando la tecnica asettica standard.
2. Prima dell'inserimento, ispezionare l'ago di Veress per assicurarsi che la cannula si sposti liberamente sull'otturatore smussato con una pressione minima applicata al dispositivo.
3. Inserire l'ago di Veress.
4. Si raccomanda di eseguire vari controlli per assicurare che l'ago di Veress si trovi nella cavità addominale, e di assicurarsi che nella finestrella di sicurezza **non** sia visibile una linea rossa.
5. Dopo aver accertato che il posizionamento sia corretto, gonfiare fino a ottenere la pressione desiderata.
6. Una volta completata l'insufflazione e ottenuta la pressione addominale desiderata, rimuovere l'ago da Veress e procedere con la procedura laparoscopica.

Precauzioni

Materiali

Tutti i componenti e gli imballaggi sono privi di ftalati e lattice.



Indicaties (beoogd gebruik)

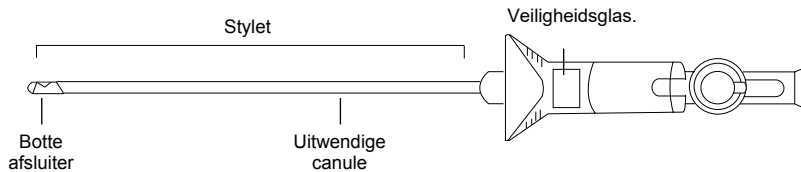
Gebruiksaanwijzingen

1. Trek het zakje open en verwijder het product met standaard, aseptische technieken.
2. Inspecteer, alvorens insertie, de Veress-naald om te verzekeren dat de canule vrij beweegt over de botte afsluiter, terwijl minimale druk wordt toegepast op het hulpmiddel.
3. Alvorens incisie van de Veress-naald, moet de chirurgische locatie grondig worden voorbereid.
4. Voer de Veress-naald in.
5. Het wordt aanbevolen om diverse controles uit te voeren, om te verzekeren dat de Veress-naald in de buikholtte is, en om te verzekeren dat de rode lijn **niet** zichtbaar is op het veiligheidsglas.
6. Zodra de juiste plaatsing is verzekerd, kan het tot de gewenste druk worden opgeblazen.
7. Zodra de insufflatie is voltooid en de gewenste buikdruk is verkregen, verwijdert u de Veress-naald en gaat u door met de laparoscopische procedure.

Voorzorgsmaatregelen

Materialen

Alle onderdelen en verpakkingen zijn latex- en ftalaatvrij.



Indikasjoner (tiltenkt bruk)

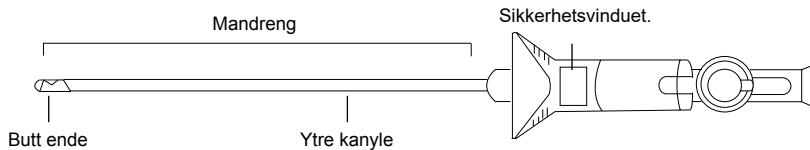
Bruksanvisning

1. Fjern posen og fjern produktet ved hjelp av standard aseptiske teknikker.
2. Før innsetting skal Veress-nålen undersøkes for å sikre at kanylen beveger seg fritt over den butte enden med minimalt trykk på enheten.
3. Sett inn Veress-nålen.
4. Det anbefales å foreta ulike kontroller for å sikre at Veress-nålen er inne i det abdominale hulrommet, og ved sikring av at den røde linjen er synlig i sikkerhetsvinduet.
5. Når korrekt plassering er fastslått, skal hulrommet blåses opp til ønsket trykk.
6. Når innblåsningen er ferdig og det ønskede abdominaltrykket er oppnådd, skal Veress-nålen fjernes og den laparoskopiske prosedyren kan fortsette.

Forsiktighetsregler

Materialer

Alle bestanddelene og emballasjen er frie for latex og ftalat.



Indicações (Utilização prevista)

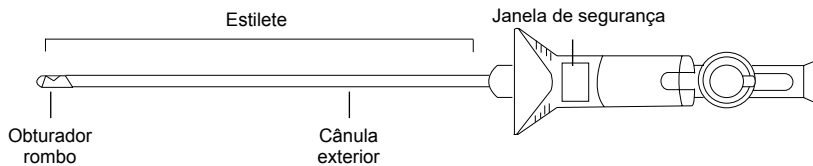
Instruções de utilização

1. Abra a bolsa e retire o produto utilizando técnicas assépticas padrão.
2. Antes da inserção, inspecionar a agulha de Veress para garantir que a cânula se move livremente através do obturador rombo, com pressão mínima aplicada ao dispositivo.
3. Introduzir a agulha de Veress.
4. Recomenda-se a realização de várias verificações para garantir que a agulha de Veress se encontre na cavidade abdominal, bem como garantir que a linha vermelha fique visível na janela de segurança.
5. Logo que seja confirmado o posicionamento correto, inflar a pressão pretendida.
6. Quando a insuflação estiver concluída e a pressão abdominal pretendida for atingida, remover a agulha

Precauções

Materiais

Todos os componentes e embalagens são isentos de látex e ftalatos



Indikationer/Avsedd användning)

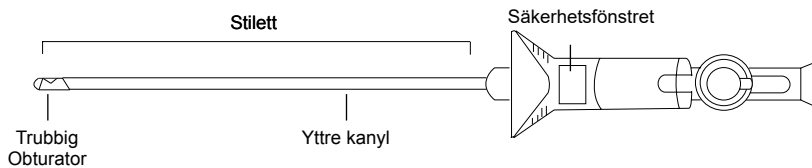
Bruksanvisning

1. Öppna påsen och ta ut produkten från innerpåsen med sedvanlig aseptisk teknik.
2. Innan insättningen inspektera Veress-nålen för att säkerställa att kanylen rör sig fritt över den trubbiga obturatorn med minimalt tryck applicerat på enheten.
3. Sätt in Veress-nålen.
4. Det rekommenderas att utföra olika kontroller för att säkerställa att Veress-nålen är i bukhålan, och att säkerställa att den röda linjen är synlig i säkerhetsfönstret.
5. När korrekt placering är fastställd, blås upp till önskat tryck.
6. När insufflationen är fullständig och det önskade abdominaltrycket uppnåtts, ta bort Veress-nålen och fortsätt med laparoskopisk procedur.

Försiktighetsåtgärder

Material

Alla komponenter och förpackningar är ftalat- och latexfria





Catalogue number



Manufacturer



Batch code



Date of manufacture



Unique device identifier



Expiry date



Is a medical device



EU Importer



Authorised representative in the European Community



Product conforms with Regulation (EU) 2017/745



Language denotation as per EC language codes



Do not use if packaging is damaged



Caution is necessary



Keep away from sunlight



Keep dry



Single use only



Do not resterilise



Non-sterile



Consult instructions for use



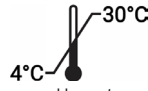
Made in Australia



Latex free



Phthalate and DEHP free



Upper and lower temperature limits



Non-pyrogenic



Single sterile barrier system with protective packaging inside, sterilised with EO

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Fairmont Medical Products Pty Ltd is certified to ISO13485:2016

PM069 Version 4.0

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