

Meniscus Mender II Disposable Suture Kit, showing the two curved spinal needles, two straight spinal needles, four stylets, and two patented suture loops.

Meniscus Mender II Disposable Suture Kit

Meniscus Mender II-Einweg-Naht-Kit

Kit de suturas desechables

Meniscus Mender II

Kit de suture jetable Meniscus Mender II

Kit usa e getta per suture

Meniscus Mender II

Meniscus Mender II sutursats för engångsbruk

Meniscus Mender II hechtkit voor eenmalig gebruik

Kit de sutura descartável

Meniscus Mender II

Meniscus Mender II sutursæt til engangsbrug

Meniscus Mender II Sutursett til engangsbruk

Meniscus Mender II 1회용 봉합 키트

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Meniscus Mender II Disposable Suture Kit

Meniscus Mender II (MMII) REF 7209485

- ☒ **STERILE** **R**

Device Description

The Smith & Nephew Meniscus Mender II Disposable Suture Kit is comprised of two curved spinal needles, two straight spinal needles, four stylets, and two patented suture loops. These components, combined with the outside-in approach, minimize the risk of damage to neurovascular structures during meniscal repair.

Indications for Use

The disposable Meniscus Mender II Kit is intended for use in the repair of torn menisci in the knee joint.

Contraindications

None known.

- ⚠ **Warnings**
- ⛔ **Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.**
- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.**
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.**

- Read these instructions completely prior to use.
- Associated instruments for the Meniscus Mender II kit are sold separately and are provided NON-STERILE. These instruments must be properly cleaned and sterilized prior to use.

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Precautions

The U.S. Federal law restricts this device to sale by or on the order of a physician.

- Reuse may result in patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Sterile technique must be exercised during surgical procedure and handling of this device. Prophylactic antibiotics may be administered at the discretion of the surgeon.

- Use of this kit is recommended only for those tears that appear in the outer one-third of the meniscus. Use in other regions of the meniscus, though not harmful, will not render the same results.
- The Meniscus Mender II Kit should be stored at room temperature.
- Careful attention must be paid to asepsis and avoidance of anatomical hazards.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

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Meniscus Mender II-Einweg-Naht-Kit

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Meniscus Mender II-Einweg-Naht-Kit

Meniscus Mender II (MMII) Best.-Nr. 7209485

- ☒ **STERILE** **R**

Produktbeschreibung

Das Smith & Nephew Meniscus Mender II-Einweg-Naht-Kit besteht aus zwei gebogenen Spinalnadeln, zwei geraden Spinalnadeln, vier Stilettis und zwei patentierten Fadenschlingen. Diese Komponenten minimieren in Verbindung mit dem Outside-in-Verfahren das Risiko einer Beschädigung neurovaskulärer Strukturen während einer Meniskusreparatur.

Indikationen

Das Einweg-Kit Meniscus Mender II ist für den Einsatz bei der Reparatur gerissener Menisken im Kniegelenk konzipiert.

Kontraindikationen

Es sind keine Kontraindikationen bekannt.

Warnhinweise

⚠ **Bei beschädigter Verpackung nicht verwenden. Bei beeinträchtigtem Sterilschutz oder beschädigter Verpackung des Produkts nicht verwenden.**

- Der Inhalt ist steril, solange die Packung ungeöffnet und unbeschädigt ist. **NICHT ERNEUT STERILISIEREN. Nur für den einmaligen Gebrauch.** Angebrochene und ungebrauchte Produktreste sind zu entsorgen. Nach Ablauf des Verfallsdatums nicht mehr verwenden.
- Es liegt in der Verantwortung des Arztes, sich vor Verwendung des Produkts mit den entsprechenden chirurgischen Techniken vertraut zu machen.
- Diese Anweisungen vor Gebrauch vollständig durchlesen.
- Zugehörige Instrumente für das Meniscus Mender II-Kit werden separat vertrieben und UNSTERIL geliefert. Diese Instrumente müssen vor dem Gebrauch sorgfältig gereinigt und sterilisiert werden.

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- Contents are sterile unless package is opened or damaged. DO NOT REESTERILIZAR. Para usar una sola vez. Descarte cualquier producto que haya sido abierto pero no utilizado. No utilizar después de la fecha de caducidad.
- Es responsabilidad del cirujano estar familiarizado con las técnicas quirúrgicas apropiadas antes del uso de este dispositivo.
- Lea estas instrucciones en su totalidad antes de usar.
- Los instrumentos asociados para el kit Meniscus Mender II se venden por separado y se proporcionan NO ESTÉRILES. Estos instrumentos deben limpiarse y esterilizarse correctamente antes de utilizarlos.

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Kit de suturas desechables Meniscus Mender II

Meniscus Mender II (MMII) N° de ref. 7209485

- ☒ **STERILE** **R**

Descripción del dispositivo

El kit de suturas desechables Meniscus Mender II de Smith & Nephew está compuesto de dos agujas espinales curvas, dos agujas espinales rectas, cuatro guías estiletes y dos bucles de sutura patentados. Estos componentes, combinados con el abordaje de afuera hacia adentro, minimizan el riesgo de ocasionar daños a las estructuras neurovasculares durante la reparación meniscal.

Indicaciones de uso

El kit desechable Meniscus Mender II está concebido para utilización en la reparación de meniscos desgarrados en la articulación de la rodilla.

Contraindicaciones

Ninguna conocida.

Advertencias

⚠ **No lo utilice si el paquete está dañado. No utilice el producto si la barrera de esterilización o su envase no están en perfecto estado.**

- El contenido es estéril a menos

Meniscus Mender II sutursats för engångsbruk

Meniscus Mender II (MMII)
Best.nr 7209485

☒ **STERILE R**

Beskrivning av produkten

The Smith & Nephew Meniscus Mender II sutursats för engångsbruk består av två krökta spinalnålar, två raka spinalnålar, fyra sonder och två patenterade suturöglor. Dessa komponenter minimerar risken för skada på neuromuskulära strukturer under meniskreparationer, om de används vid procedurer utifrån och in.

Indikationer

Engångssatsen Meniscus Mender II är avsedd för reparation av trasiga menisker i knäleder.

Kontraindikationer

Inga kända.

Varningar

☒ Använd inte produkten om förpackningen är skadad. Använd inte produkten om dess sterilbarriär eller förpackning är bruten.

- Innehållet är sterilt under förutsättning att förpackningen är öopppnad och oskadad. FÅR EJ RESTERILISERAS. Endast för engångsbruk. Kassera alla öppnade, oanvända produkter. Får ej användas efter utgångsdatumet.

- Det åligger kirurgen att göra sig förtrogen med lämpliga operationstekniker före användning av denna produkt.

- Läs igenom dessa anvisningar i sin helhet före användning.

- Associerade instrument för satsen Meniscus Mender II säljs separat och levereras ICKE-STERILA. Dessa instrument måste rengöras och steriliseras ordentligt före användning.

Försiktighetsåtgärder

☒ Enligt federal lagstiftning (USA) får denna produkt endast säljas av läkare eller på läkares ordination.

- Återanvändning kan medföra patientinfektion och/eller felfunktion hos anordningen.

- Inspektera produkten före användning för att säkerställa att den inte är skadad. Använd inte en skadad produkt.

- Sterilteknik skall utövas under operationen och vid hantering av detta instrument. Profylaktisk antibiotika kan administreras enligt kirurgens bedömning.

- Vi rekommenderar endast denna sats för skador i meniskens yttre tredjedel. Användning inom andra områden av menisken är inte skadlig, men kommer inte att ge samma resultat.

- Meniscus Mender II-satsen skall förvaras vid rumstemperatur.

- Noggrann uppmärksamhet skall ägnas åt asepsis och undvikande av anatomiska risker.

- Efter användning kan denna produkt utgöra biologiskt riskavfall och skall hanteras enligt vedertagen sjukhuspraxis och tillämpliga lokala och nationella fördordningar.

Garanti

Endast för engångsbruk. Denna produkt garanteras vara fri från defekter vad beträffar material och utförande. Får ej återanvändas.

Ytterligare information

Kontakta din lokala representant för Smith & Nephew om ytterligare information behövs om denna produkt.

Meniscus Mender II hechtkit voor eenmalig gebruik

Meniscus Mender II (MMII)
REF 7209485

☒ **STERILE R**

Beschrijving van het product

De Smith & Nephew Meniscus Mender II hechtkit voor eenmalig gebruik bestaat uit twee gebogen spinale naalden, twee rechte spinale naalden, vier stilleten en twee gepatenteerde hechtdraadlussen. Deze onderdelen, in combinatie met de benadering vanaf de buitenzijde, minimaliseren het risico op beschadiging van neurovasculaire structuren tijdens een meniscusingreep.

Indicaties voor gebruik

De Meniscus Mender II kit voor eenmalig gebruik is bedoeld voor gebruik bij het herstellen van gescheurde meniscussen in het kniegewricht.

Contra-indicaties

Geen bekend.

⚠️ Waarschuwingen

☒ **Niet gebruiken als de verpakking is beschadigd. Niet gebruiken als de steriele afdichting van het product of de verpakking ervan is aangetast.**

- Inhoud steriel tenzij verpakking beschadigd of reeds geopend is. NIET OPNIEUW STERILISEREN. Uitsluitend bestemd voor eenmalig gebruik. Geopende doch ongebruikte producten wegwerpen. Niet gebruiken na het verstrijken van de uiterste gebruiksdatum.

- Het is de verantwoordelijkheid van de chirurg zich vertrouwd te maken met de operatietechnieken die met het gebruik van dit instrument samenhangen alvorens het instrument te gebruiken.

- Deze instructies vóór gebruik geheel doorlezen.

- Instrumenten horend bij de Meniscus Mender II kit worden afzonderlijk verkocht en worden NIET STERIEL geleverd. Deze instrumenten moeten vóór gebruik op de juiste wijze worden gereinigd en gesteriliseerd.

Voorzorgsmaatregelen

☒ Volgens de Amerikaanse wetgeving mag dit product alleen door of op voorschrift van een arts worden verkocht.

- Hergebruik kan tot infectie van de patiënt en/of storing in het apparaat leiden.

- Inspecteer het product vóór gebruik om te zien of het niet beschadigd is. U mag een beschadigd product niet gebruiken.

- Gedurende de chirurgische procedure en bij de behandeling van dit product moet gebruik worden gemaakt van een steriele techniek. Er mogen profylactische antibiotica worden toegediend als de chirurg dit nodig acht.

- Het gebruik van deze kit wordt uitsluitend aanbevolen voor scheuren in het buitenste eenderde deel van de meniscus. Het gebruik op andere plaatsen van de meniscus zal niet hetzelfde resultaat opleveren, maar heeft geen schadelijke gevolgen.

- De Meniscus Mender II kit moet bij kamertemperatuur worden bewaard.

- Er moet zorgvuldig aandacht worden besteed aan asepsis en het voorkomen van anatomische schade.

- Na gebruik kan dit product een biorisico vormen en dient het behandeld te worden volgens algemeen aanvaard medisch protocol en de van toepassing zijnde plaatselijke en landelijke vereisten.

Garantievoorwaarden

Uitsluitend bestemd voor eenmalig gebruik. Er wordt gegarandeerd dat dit product vrij is van defecten in materiaal en fabricage. Niet nogmaals gebruiken.

Nadere informatie

Neem voor nadere informatie over dit product contact op met de erkende vertegenwoordiger van Smith & Nephew.

Kit de sutura descartável Meniscus Mender II

Meniscus Mender II (MMII)

N.º de ref. 7209485

☒ **STERILE R**

Descrição do dispositivo

O kit de sutura descartável Meniscus Mender II da Smith & Nephew é constituído por duas agulhas espinais curvas, duas agulhas espinais rectas, quatro estiletos e duas alças de sutura patenteadas. Estes componentes, em combinação com a abordagem de fora para dentro, minimizam o risco de danos nas estruturas neurovasculares durante a reparação do menisco.

Indicações de utilização

O kit descartável Meniscus Mender II está indicado para utilização na reparação de rotura de meniscos na articulação do joelho.

Contra-indicações

Nenhuma conhecida.

⚠️ Advertências

☒ **Não utilize se a embalagem apresentar danos. Não utilize se a barreira de esterilização ou a embalagem do produto estiverem danificadas.**

- O conteúdo está esterilizado, salvo se a embalagem tiver sido aberta ou danificada. NÃO VOLTE A ESTERILIZAR. Apenas para utilização única. Elimine qualquer produto aberto não utilizado. Não utilize após expirado o prazo de validade.

- É da responsabilidade do cirurgião estar familiarizado com as técnicas cirúrgicas adequadas antes de proceder à utilização deste dispositivo.

- Leia estas instruções na íntegra antes da utilização.

Meniscus Mender II sutursæt til engangsbrug

Meniscus Mender II (MMII)
REF 7209485

☒ **STERILE R**

Beskrivelse af anordningen

Smith & Nephew Meniscus Mender II sutursæt til engangsbrug består af to krumme spinalnåle, to lige spinalnåle, fire stiletter og to patenterede suturløkker. Disse komponentene, sammen med en utover/innover-metode, minimaliserer risikoen for å skade neurovaskulære strukturer under reparasjon av menisken.

Indikationer

Meniscus Mender II sutursættet til engangsbrug er beregnet til anvendelse ved reparationer af menisklæsioner i knæleddet.

Kontraindikationer

Ingen kendte.

⚠️ Advarsler

☒ **Produktet må ikke anvendes, hvis emballagen er beskadiget. Må ikke bruges, hvis produktets sterilisationsbarriere eller emballage er beskadiget.**

- Indholdet er sterilt, medmindre emballagen er åbnet eller beskadiget. **MÅ IKKE RESTERILISERES.** Kun til engangsbrug. Bortskaf alle åbnede, ubrugte materialer. Må ikke anvendes efter udløbsdatoen.

- Det er kirurgens ansvar at være fortrolig med de rette operationsteknikker, før produktet tages i brug.

- Læs alle anvisninger inden brug.

- Instrumenter til anvendelse med Meniscus Mender II sutursættet sælges særskilt og leveres USTERILE. Disse instrumenter skal rengøres og steriliseres grundigt før brug.

Meniscus Mender II Sutursett til engangsbrug

Meniscus Mender II (MMII)
REF 7209485

☒ **STERILE R**

Beskrivelse av innretningen

Smith & Nephew Meniscus Mender II kirurgiske inngrepet og ved håndtering av utstyret. Profylaktiske antibiotika kan administreres etter kirurgens skjønn.

- Det anbefales at dette settet bare brukes ved rifter som forekommer i den ytterste tredjedelen av menisken. Bruk i andre områder vil ikke gi de samme resultatene, selv om det ikke er skadelig.

- Meniscus Mender II-settet skal oppbevares ved romtemperatur.

- Bruk aseptisk teknikk for å unngå anatomisk risiko.

- Etter bruk kan dette utstyret utgjøre en mulig biologisk risiko, og skal håndteres i samsvar med akseptert medisinsk praksis og gjeldende lokale og nasjonale forordninger.

Indikasjoner for bruk

Meniscus Mender II Sutursett til engangsbrug er indisert for reparasjon av avreven menisk i knæleddet.

Kontraindikasjoner

Ingen kjente.

⚠️ Advarsler

☒ **Bruk ikke utstyret hvis pakningen er skadet. Bruk ikke utstyret hvis den sterile barrieren eller emballasjen er brutt.**

- Innholdet er sterilt med mindre pakningen er åpnet eller skadet. **MÅ IKKE RESTERILISERES.** Kun til engangsbruk. Åpnet, ubrukt produkt skal kasseres. Må ikke brukes etter utløpsdatoen.

- Kirurgen er ansvarlig for å sette seg inn i egnede kirurgiske teknikker før bruk av dette utstyret.

- Les bruksanvisningen nøye før bruk.

- Tilleggsinstrumenter for Meniscus Mender II-settet selges separat og leveres IKKE-STERILE. Disse instrumentene må rengjøres på riktig måte og steriliseres før bruk.

Meniscus Mender II회용 봉합 키트

Meniscus Mender II (MMII)
참조번호 : 7209485

☒ **STERILE R**

기기 설명

Smith & Nephew Meniscus Mender II 1회용 봉합 키트는 곡선형 척수용 바늘 2개, 직선형 척수용 바늘 2개, 탐침 4개, 특허를 획득한 봉합 루프 2개로 구성되어 있습니다. 각 내용물은 악물 및 외과 치료와 결합되어 반월 연골 봉합 동안 신경혈관 구조에 대한 손상의 위험을 최소화시켜 줍니다.

적용 사항

본 1회용 Meniscus Mender II 키트는 무릎 관절의 반월 연골 복구에 사용하도록 고안되었습니다.

금지 사항

알려진 바 없음.

⚠️ 경고

☒ **포장이 손상된 경우 사용하지 마십시오. 제품의 무균 상태나 포장기 손상된 경우 사용하지 마십시오.**

- 내용물은 패키지가 개봉되어 있거나 손상되지 않는 한 무균 상태입니다. 재소독하지 마십시오. 본 제품은 1회 사용으로 제한됩니다. 개봉되었으나 사용하지 않은 제품은 폐기하십시오.

- 외과위는 이 장치를 사용하기 전에 필요한 수술 테크닉을 익혀야 합니다.

- 사용하기 전에 이 사용 지침을 잘 읽으십시오.

- Meniscus Mender II 키트의 관련 기구들은 별도로 판매되며 비살균 상태로 공급됩니다. 이 기구들은 사용 전에 적절한 세척 및 살균 과정을 거쳐야 합니다.

유의 사항

☒ 미연방법은 이 기기를 의사가 판매하거나 또는 의사의 지시 하에 판매하도록 제한하고 있습니다.

- 재사용할 경우 환자 감염 및/또는 제품 기능 장애를 초래할 수 있습니다.

- 사용에 앞서 제품이 손상되지 않았는지 검사하십시오. 손상된 제품은 사용하지 마십시오.

- 수술 과정 및 이 기구를 사용하는 동안 살균법을 시행해야 합니다. 수술의 판단 하에 예방적 항균제가 사용될 수도 있습니다.

- 반월 연골의 외측 1/3 내에 파열이 있을 경우에만 이 키트의 사용을 권장합니다. 해롭지는 않지만 반월의 다른 부위에 사용할 경우 동일한 결과를 얻지 못합니다.

- Meniscus Mender II 키트는 상온에서 보관해야 합니다.

- 무균 상태를 유지하고 해부학적 위험을 방지하기 위해 각별히 주의해야 합니다.

- 본 제품은 생물학적 위험의 가능성이 있을 수 있으므로 사용 후 의학적 실무 기준, 해당 및 지역국가의 요구 사항에 의거하여 처리되어야 합니다.

제품 보증

본 제품은 1회 사용으로 제한됩니다. 본 제품은 소재나 공정상의 결함이 없음을 보장합니다. 재사용하지 마십시오.

추가 정보

본 제품에 대한 추가 정보를 원하시는 분은 Smith & Nephew 고객 서비스 센터로 연락하시거나 해당 국가의 공인 대리점에 문의하시기 바랍니다.