



Instructions For Use

Dynamic Tissue Systems

REF CWK02A



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Rx Only



STERILE R



Not made with natural rubber latex.

MADE IN CANADA

ABRA® Surgical Skin Closure Set

Surgical Skin Set is designed to close skin defects up to 20 cm long with a medium to high force.

Indications

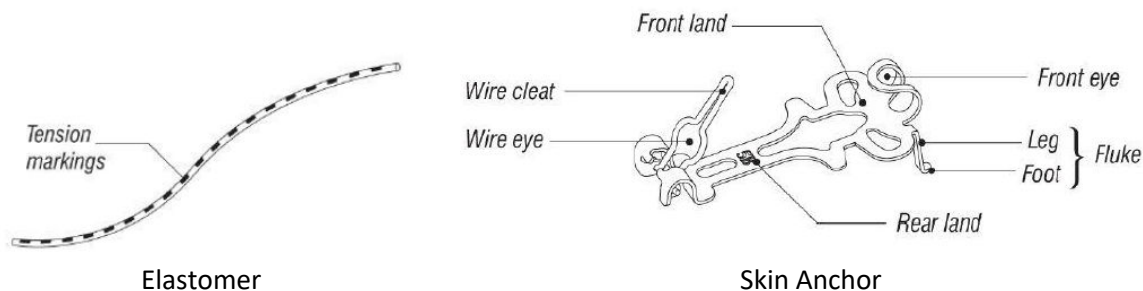
Indicated for use in controlling, reducing or closing retracted soft tissue defects.

Warnings

Must not be left on for more than 29 days.

Single use product not to be reused due to effect on performance, cross contamination, and risk of infection.

Overview





Instructions For Use

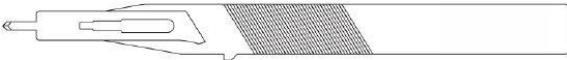
Wound Bed Preparation

If wound is fresh and margins mobile, skip step. Otherwise:

- Excise inverted wound margins.
- Remove all granulation tissue.
- Undermine wound edges by 2 cm.

Installation

Obtain Instruments

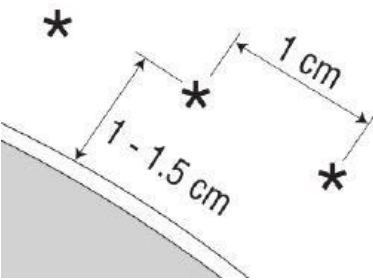


Lancet

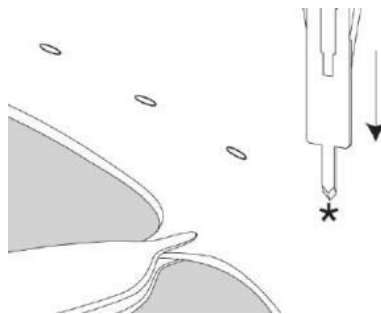


Loop Canulator

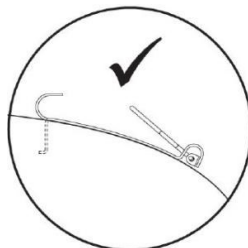
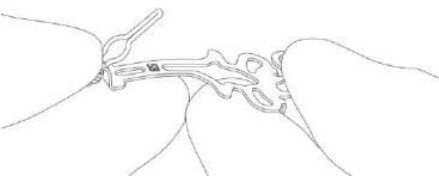
Mark Skin



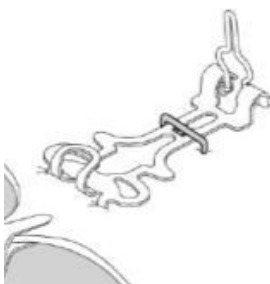
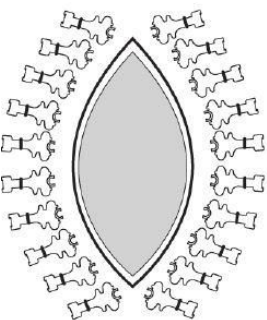
Make Fluke Holes



Contour Anchors



Place Anchors



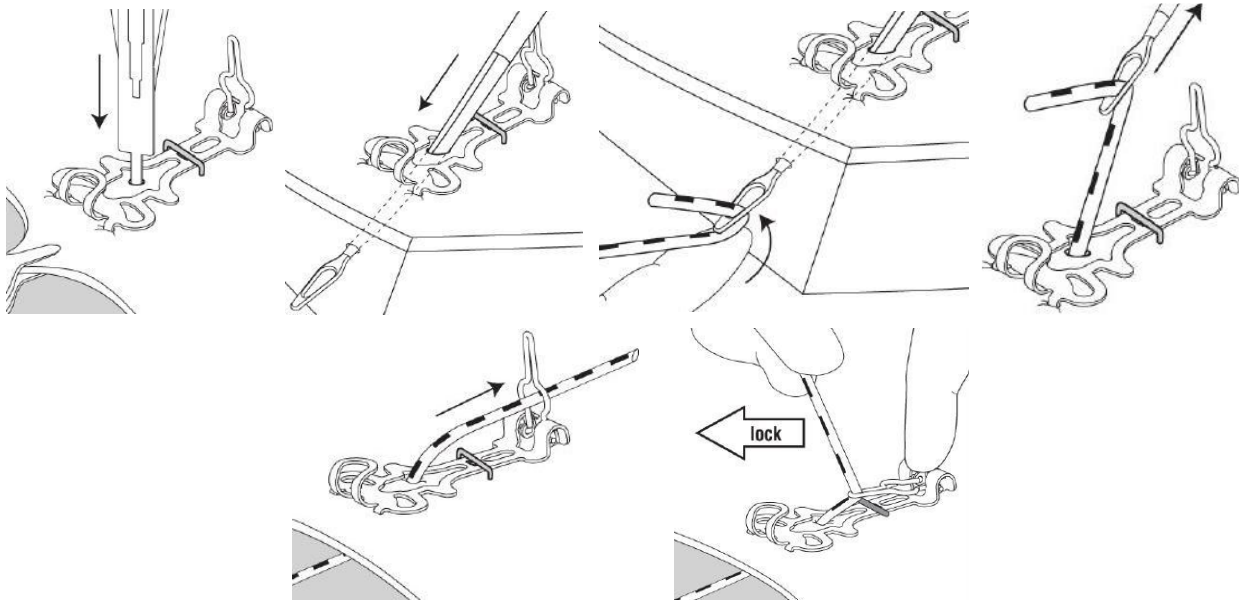
Staples



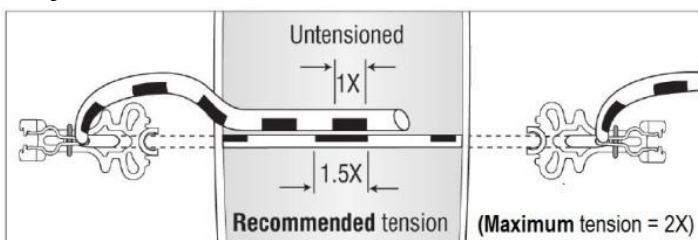
Sutures



Secure Elastomer

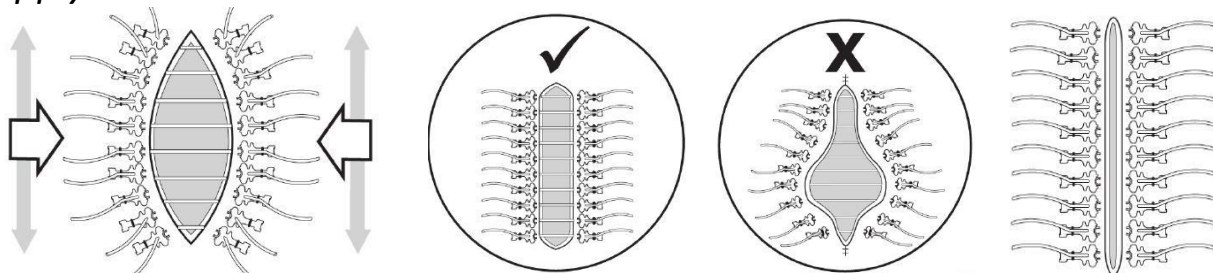


Adjust Elastomer Tension



Post-Installation Care

Apply Tension to Wound



Critical Points

- Therapeutic benefit is derived from cumulative reduction force applied by all Elastomers.
- Over-tensioning any individual Elastomer will result in unnecessary localized trauma creating individual Anchor failure, thereby transferring additional load to remaining Anchors, creating a cascade toward general System failure.
- Wound movement of several centimeters following respiration cycles or body movement is normal with dynamically closing wounds, and indicative of correct overall tension. Movement will reduce as wound approaches closure.
- Do not place any restrictive device on top of System – especially an abdominal binder or pressure stocking – as it will limit the therapeutic effect and may create traumatic pressures on skin.
- Do not restrain or knot Elastomer end behind cleat of any Anchor.



Mode d'utilisation



ABRA® Set chirurgical cutané pour la fermeture des plaies

Le Set chirurgical cutané pour la fermeture des plaies est conçu pour fermer les plaies cutanées mesurant jusqu'à 20 cm de long, avec une force de fermeture moyenne à élevée.

Indications

Les Systèmes de fermeture dynamique des plaies sont indiqués pour être utilisés afin de contrôler, diminuer ou fermer les plaies rétractées.

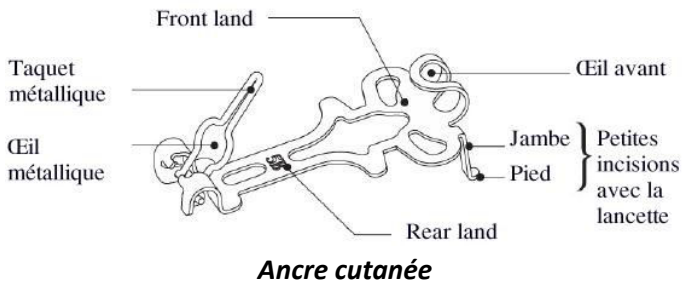
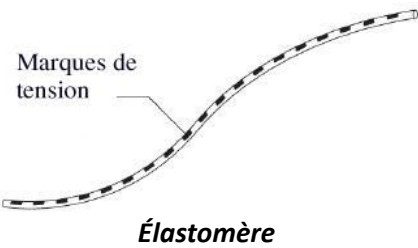
Avertissement



Ne doit pas être laissé en place pour plus de 29 jours.

Il s'agit d'un produit à usage unique; sa réutilisation risquerait une infection ou une contamination croisée ou encore le rendement affaibli du produit.

Présentation



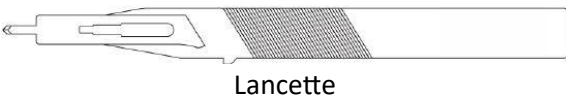
Préparation du lit de la plaie

Si la plaie est fraîche et les berges mobiles, passer outre cette étape. Autrement:

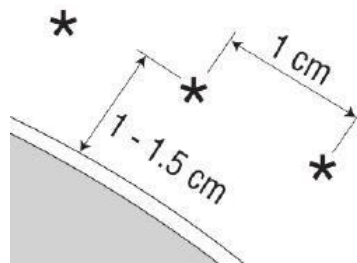
- Exciser les berges inversées de la plaie.
- Enlever tous les tissus de granulation.
- Neutraliser les bords de la plaie de 2 cm.

Installation

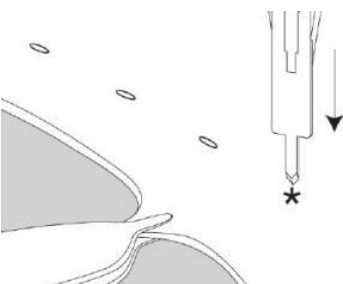
Obtenir les instruments



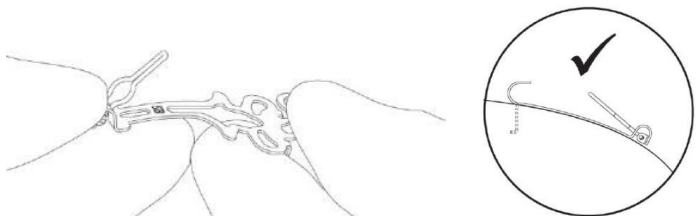
Marquer la peau



Faire de petites incisions avec la lancette

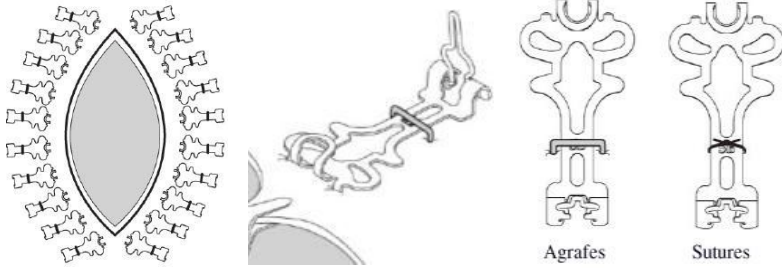


Courber légèrement les ancrs

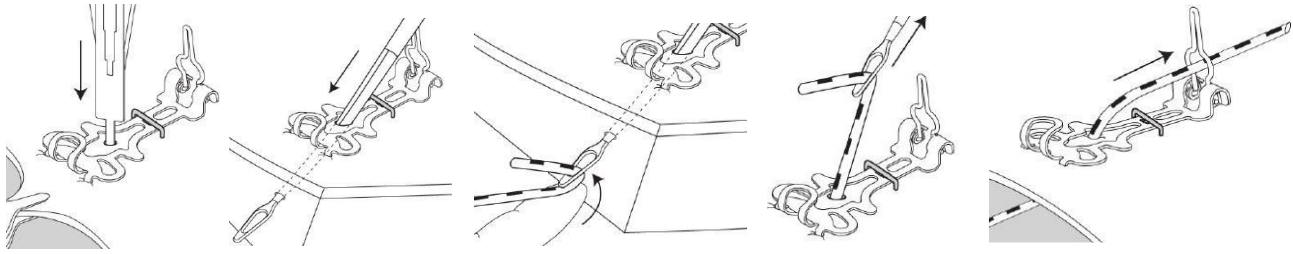




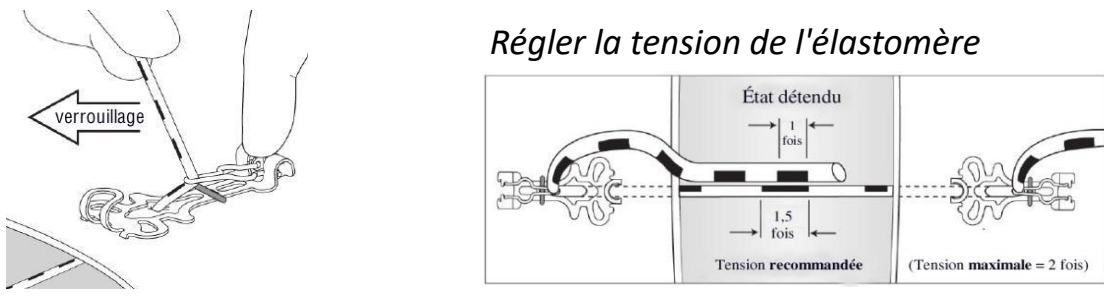
Insérer les ancres



Sécuriser l'élastomère

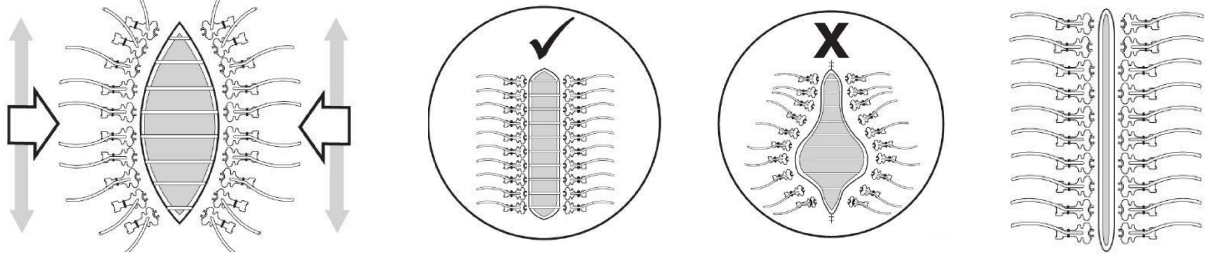


Régler la tension de l'élastomère



Soins post-installation

Appliquer la tension à la plaie



Points critiques

- Le bénéfice thérapeutique est fondé sur la réduction de la force cumulative appliquée par l'ensemble des élastomères.
- L'application sur un élastomère donné d'une tension trop élevée se traduira par un traumatisme localisé non nécessaire, ce qui a son tour aura pour conséquence l'échec de cette ancre et le transfert d'une charge supplémentaire sur les autres ancrs, créant ainsi une cascade qui aboutira à une défaillance générale du système.
- Un mouvement de la plaie de quelques centimètres à la suite des cycles respiratoires ou des mouvements du corps est normal avec les plaies se fermant dynamiquement et est indicatif d'une tension globale adéquate. Le mouvement s'estompera au fur et à mesure que la plaie se refermera.
- Ne pas placer de dispositif restrictif sur le système – en particulier une ceinture abdominale ou une ceinture de contention – car celui-ci limitera l'effet thérapeutique et suscitera des pressions traumatiques sur la peau.
- Ne pas restreindre ou nouer les extrémités de l'élastomère derrière le taquet de l'ancre.



Instrucciones de uso

ABRA® Equipo quirúrgico de cierre cutáneo

El equipo quirúrgico cutáneo está diseñado para cerrar lesiones cutáneas de hasta 20 cm de longitud con una fuerza media o alta.

Indicaciones

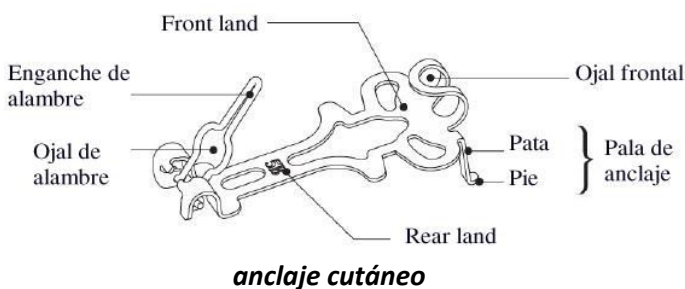
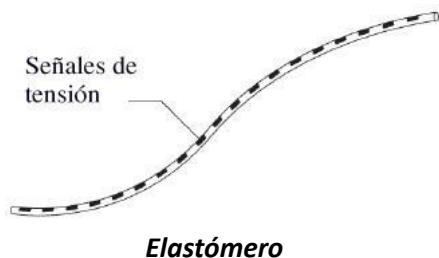
Los sistemas dinámicos de cierre de heridas están indicados para controlar, reducir y cerrar lesiones retraídas en tejidos blandos.

Advertencias

No se deben dejar puestos durante más de 29 días.

Producto de un solo uso que no debe ser reutilizado debido al efecto sobre el rendimiento, la contaminación cruzada, y el riesgo de infección.

Descripción general



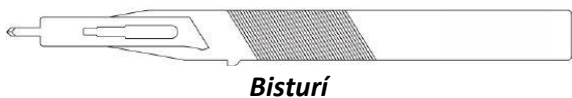
Preparación del lecho de la herida

Si la herida es fresca y sus bordes son móviles, salte este paso. En caso contrario:

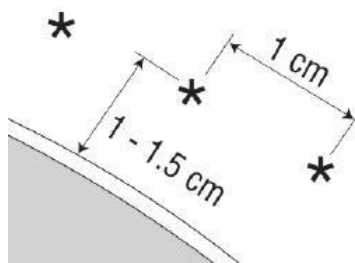
- Extirpe los bordes invertidos de la herida.
- Retire todo el tejido de granulación.
- Socave 2 cm el borde de la herida.

Instalación

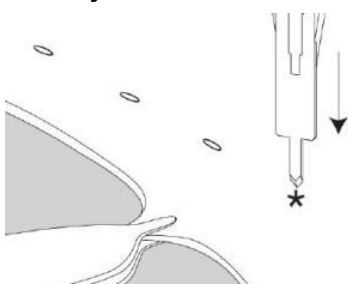
Obtener instrumentos



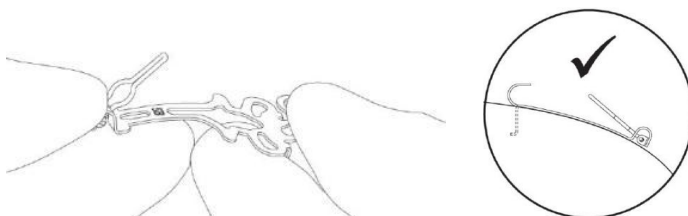
Señalar la piel



Perforar para la pala del anclaje

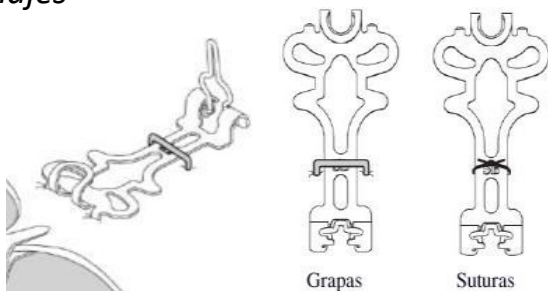
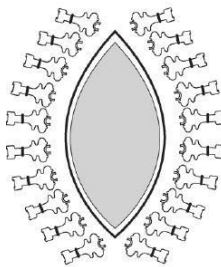


Anclajes de contorno

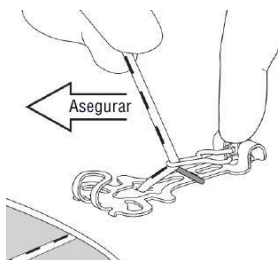
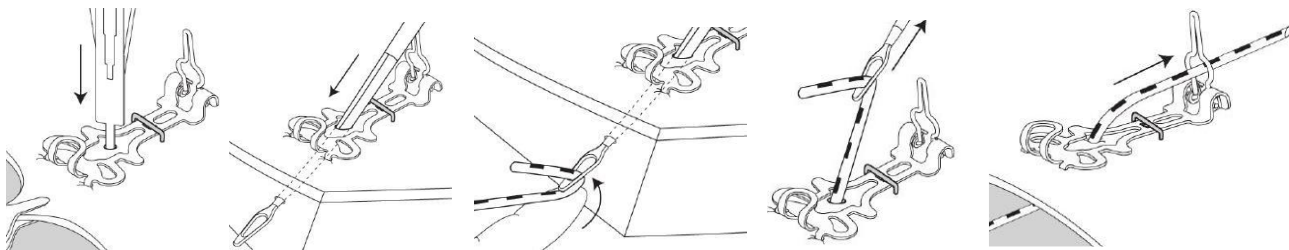




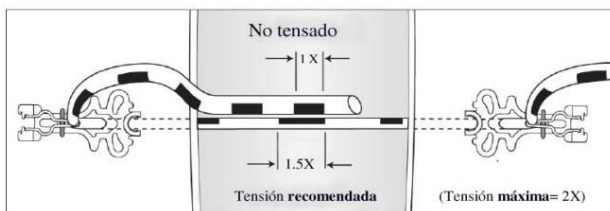
Colocar los anclajes



Asegurar el elastómero

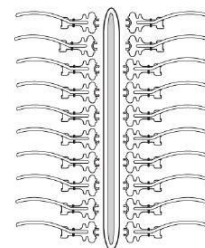
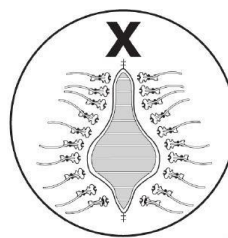
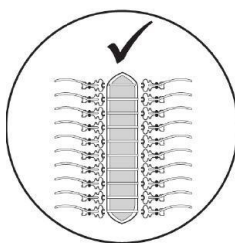
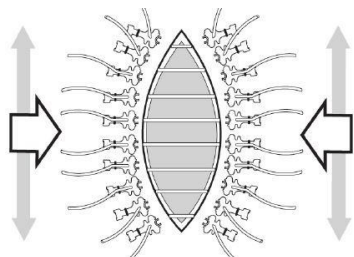


Ajustar la tensión del elastómero



Cuidado posterior a la instalación

Aplicar tensión a la herida



Aspectos fundamentales

- Los beneficios terapéuticos se derivan de la reducción acumulativa de fuerza ejercida por todos los elastómeros.
- Una tensión excesiva en alguno de los elastómeros resultaría en un traumatismo localizado innecesario, que haría fallar uno de los anclajes y, de este modo, transferiría carga adicional a los demás anclajes, desencadenando un fallo general del sistema.
- Tras los ciclos de respiración o movimientos corporales, en el caso de heridas que se cierran de forma dinámica, es normal que la herida se mueva varios centímetros, lo que indica una tensión general correcta. El movimiento se reducirá a medida que se aproxime el cierre de la herida.
- No coloque ningún dispositivo restrictivo sobre el sistema, especialmente fajas abdominales o medias elásticas, pues podría limitar el efecto terapéutico y crear presiones traumáticas en la piel.
- No sujete ni anude el extremo del elastómero que se encuentra detrás del enganche de cualquiera de los anclajes



Gebrauchsanweisung

ABRA® Chirurgisches Hautverschlussset

Das chirurgische Hautset ist dafür ausgelegt, Hautdefekte von bis zu 20 cm Länge mit mittlerer bis hoher Kraft zu schließen.

Indikationen

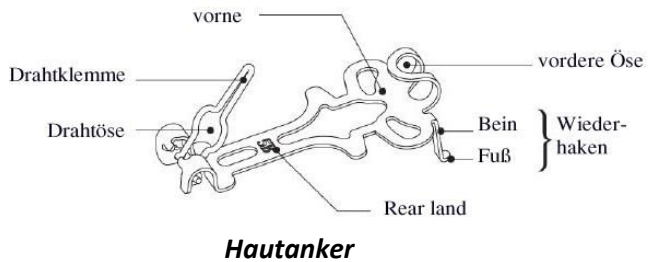
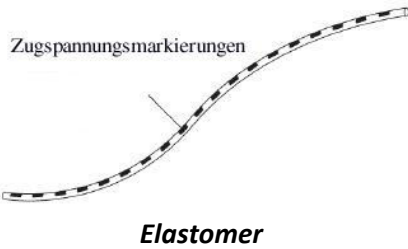
Der Einsatz von dynamischen Wundverschlussystemen ist angezeigt, wenn zurückziehende Weichgewebedefekte beherrscht, reduziert oder geschlossen werden sollen.

Warnhinweise

Darf nicht länger als 29 Tage am Patienten verbleiben.

Produkt nur zum Einmalgebrauch - wegen Leistungsauswirkung, Kreuzkontaminierung und Infektionsrisiko nicht wiederverwenden.

Überblick



Wundbettvorbereitung

Falls die Wunde frisch und die Randsäume mobil sind, überspringen Sie diesen Schritt. Ansonsten:

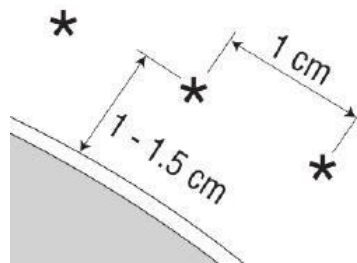
- Exzidieren Sie invertierte Wundränder.
- Entfernen Sie granuliertes Gewebe.
- Unterhöhlen Sie die Wundränder um 2 cm.

Installation

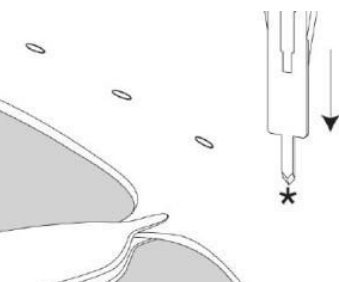
Erforderliche Instrumente



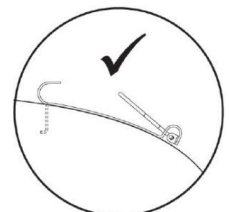
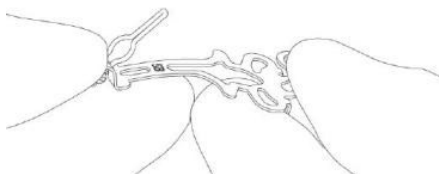
Haut markieren



Löcher für Widerhaken markieren

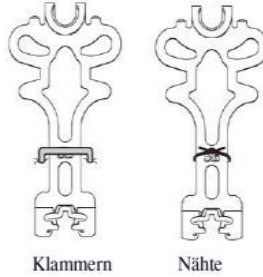
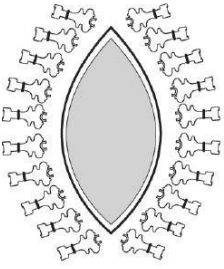


Anker umreißen

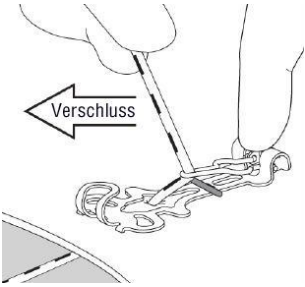
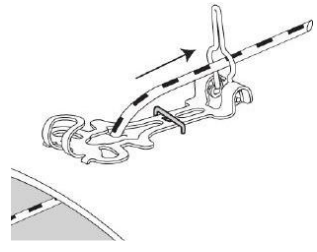
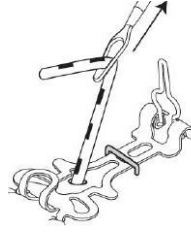
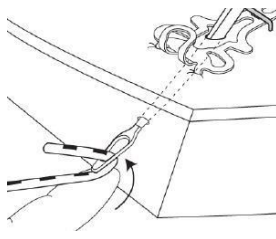
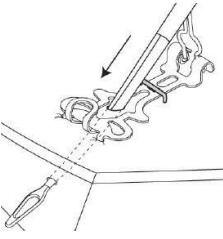
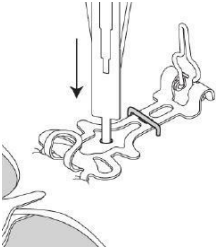




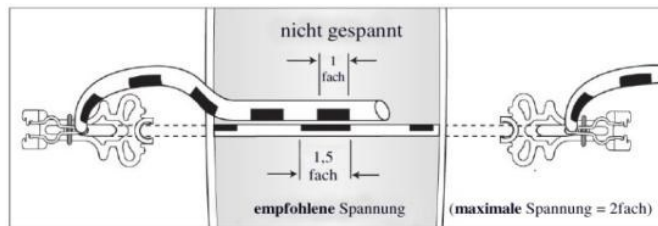
Anker platzieren



Elastomer befestigen

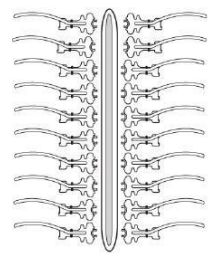
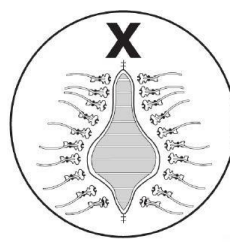
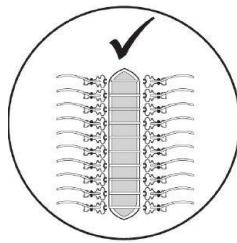
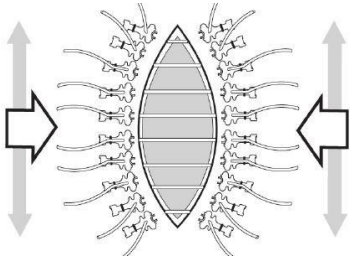


Elastomerspannung justieren



Versorgung nach der Installation

Spannung auf Wunde ausüben



Wichtige Punkte

- Therapeutischer Nutzen ergibt sich aus der kumulativen Reduktionskraft, die von allen Elastomeren ausgeübt wird.
- Eine zu große Spannung auf einem einzelnen Elastomer führt zu einem unnötigen örtlichen Trauma, das wiederum zu einem Versagen des betroffenen Ankers führt. Daraufhin wird zusätzliche Kraft auf die verbleibenden Anker ausgeübt. Dies kann in der Folge zu einer Fehlerkaskade bis hin zum vollständigen Ausfall des Systems führen.
- Wundbewegungen von mehreren Zentimetern aufgrund von Respirationszyklen oder Körperbewegungen sind normal bei sich dynamisch schließenden Wunden und sind ein Hinweis auf eine korrekte Gesamtspannung. Die Bewegung lässt mit zunehmendem Wundverschluss nach.
- Platzieren Sie keine beengende Vorrichtungen auf dem System – insbesondere keine abdominalen Binder oder Kompressionsverbände. Dies würde die therapeutische Wirkung vermindern und kann zu traumatischen Belastungen der Haut führen.
- Die Elastomerenden hinter der Klemme eines Ankers dürfen weder beschränkt noch verknotet werden.



Istruzioni per l'uso



ABRA® Surgical Skin Closure Set

Il set per la chiusura chirurgica della cute è progettato per la chiusura di difetti cutanei di lunghezza massima pari a 20 cm con una forza medio-alta.

Indicazioni

I sistemi per la chiusura dinamica delle ferite sono indicati all'uso per il controllo, la riduzione o la chiusura di difetti causati dalla retrazione di tessuti molli.

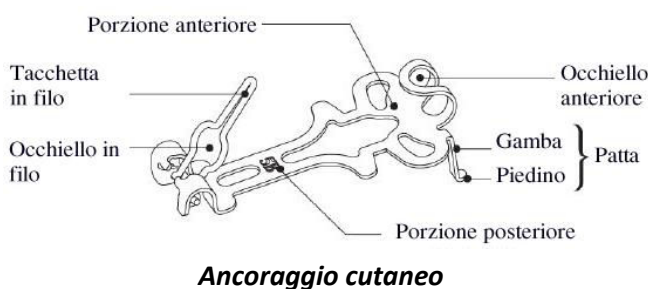
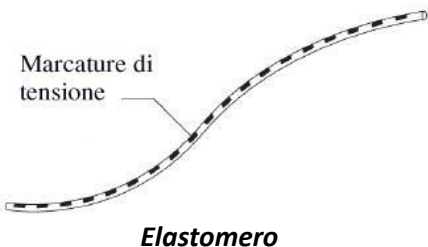
Avvertenze



I sistemi non devono essere lasciati in sede per più di 29 giorni.

Prodotto monouso da non riutilizzare a causa della riduzione di prestazioni, contaminazione incrociata e rischio d'infezione.

Panoramica



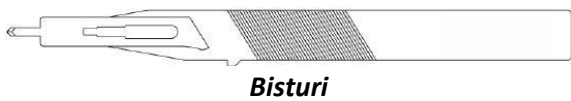
Preparazione del letto della ferita

Se la ferita è fresca con margini mobili, saltare questo passaggio. Diversamente:

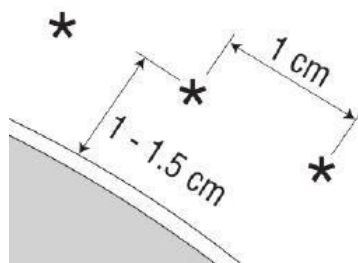
- Asportare i margini invertiti della ferita.
- Rimuovere tutto il tessuto di granulazione.
- Cavitare i margini della ferita di 2 cm.

Applicazione del

Strumenti necessari

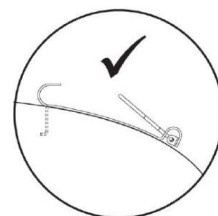
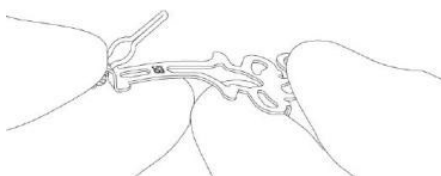
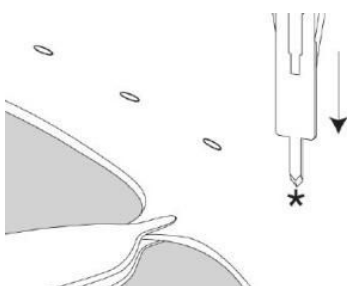


Marcare la cute



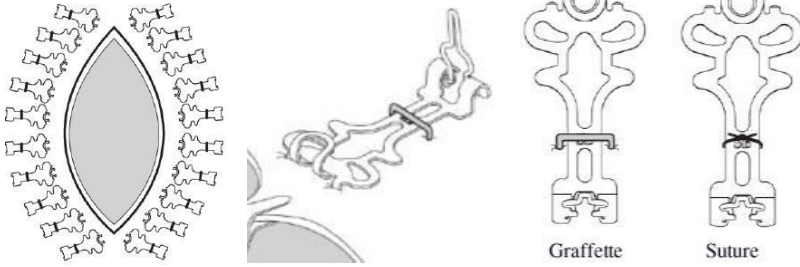
Praticare i fori di ancoraggio

Preparazione degli ancoraggi

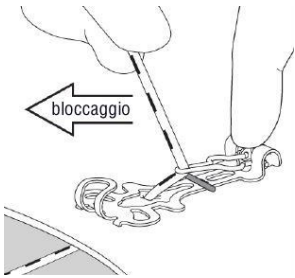
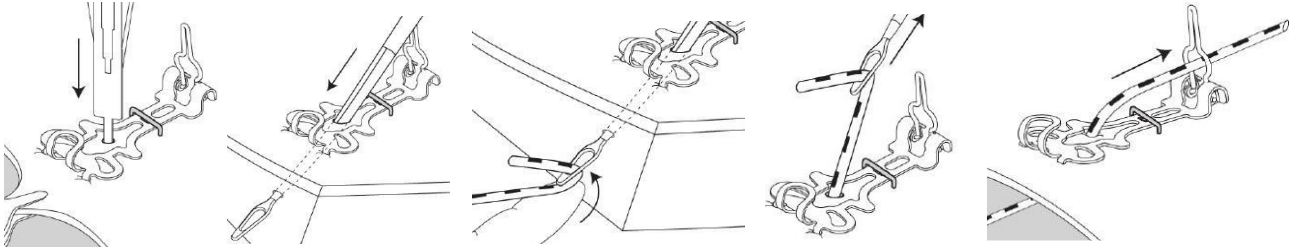




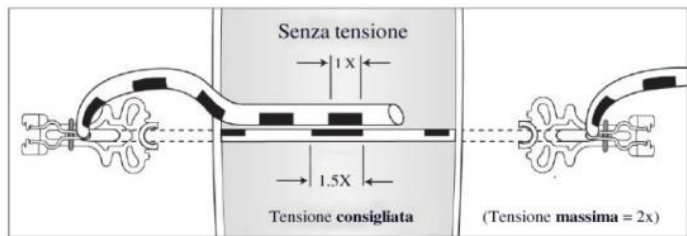
Applicazione degli ancoraggi



Fissazione dell'elastomero

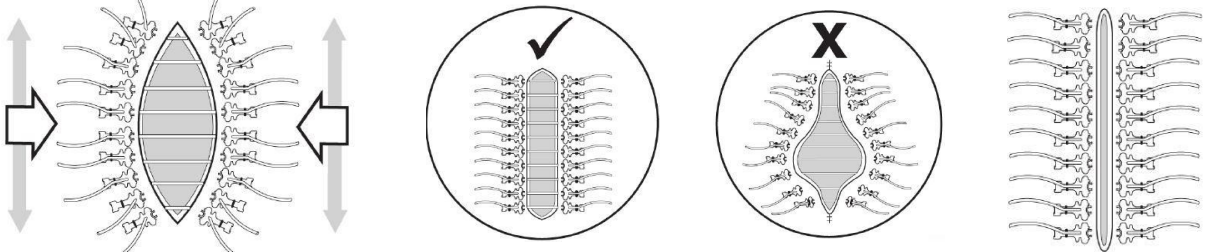


Regolazione della tensione dell'elastomero



Cura post-applicazione

Applicare la tensione alla ferita



Punti salient

- Il beneficio terapeutico è il risultato dalla forza cumulativa applicata da tutti gli elastomeri.
- La tensione eccessiva di qualsiasi elastomero individuale risulta in un trauma localizzato non necessario, che provoca in tal modo il fallimento degli ancoraggi individuali. Ciò a sua volta causa il trasferimento di un carico aggiuntivo sugli altri ancoraggi, creando un processo a cascata che risulta nel fallimento generale del sistema.
- Il movimento di diversi centimetri della ferita a seguito dei cicli respiratori o del movimento corporeo è un evento normale con le ferite a chiusura dinamica ed è indicativo di una tensione globale adeguata. Tale movimento si riduce man mano che la ferita tende a chiudersi.
- Non collocare alcun dispositivo restrittivo sul sistema, specialmente nel caso di una fascia elastica addominale o di una calza compressiva, poiché ciò riduce l'effetto terapeutico e può generare una pressione traumatica sulla cute.
- Non bloccare né annodare l'estremità dell'elastomero oltre la tacchetta dell'ancoraggio.



Gebruiksaanwijzing

ABRA® Chirurgische huidsluitset

De Chirurgische huidset dient voor sluiting van huiddefecten met lengte van maximaal 20 cm met middelgrote tot grote kracht.

Indicaties

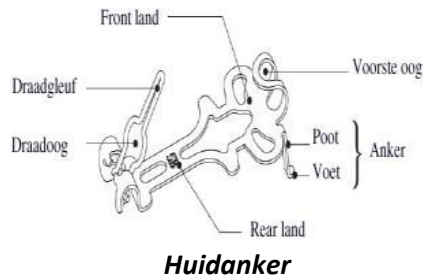
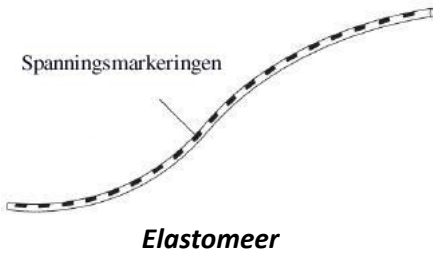
De dynamische wondsluitingssystemen zijn geïndiceerd voor gebruik bij het op zijn plaats houden, reduceren of sluiten van getraheerde defecten in weke delen.

Waarschuwingen

Niet langer dan 29 dagen laten zitten.

Product voor eenmalig gebruik. Mag niet opnieuw worden gebruikt wegens nadelig effect op prestaties, kruisbesmetting en infectiegevaar.

Overzicht



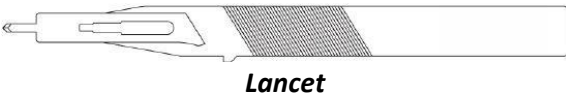
Vorbereiding van het wondbed

Deze stap kan worden overgeslagen als de wond vers is en de wondranden mobiel zijn. In alle andere gevallen:

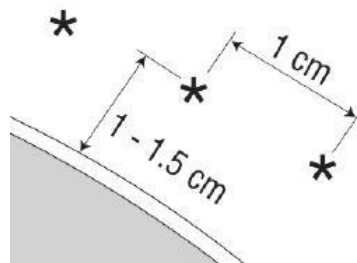
- Excideer de geïnverteerde wondranden.
- Verwijder al het gratunatieweefsel.
- Scheid de huidranden over een afstand van 2 cm van het onderliggende stroma.

Plaatsing

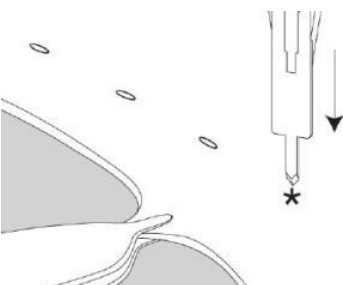
Zorg voor de juiste instrumenten



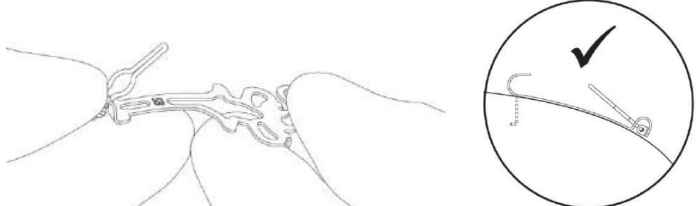
Markeer de huid



Maak de anker gaten

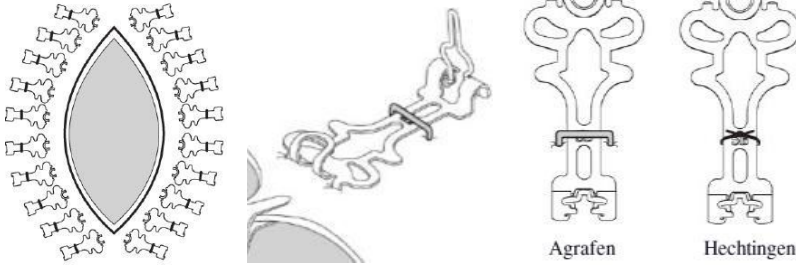


Vorm de ankers bij

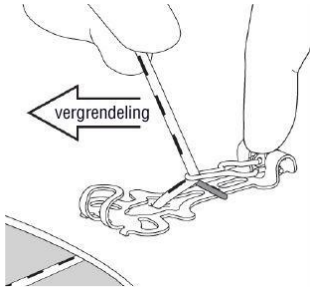
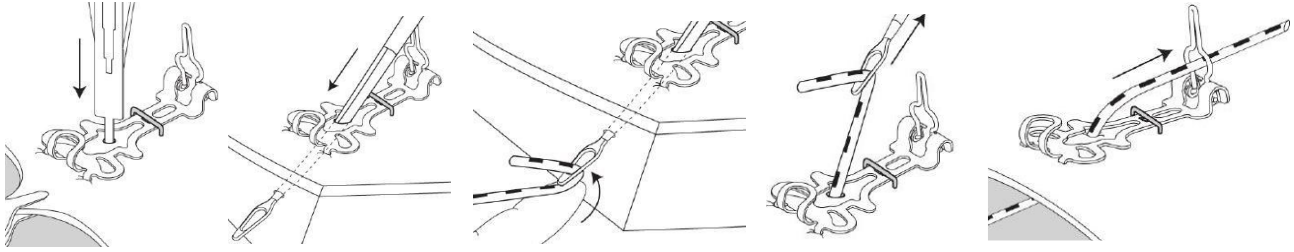




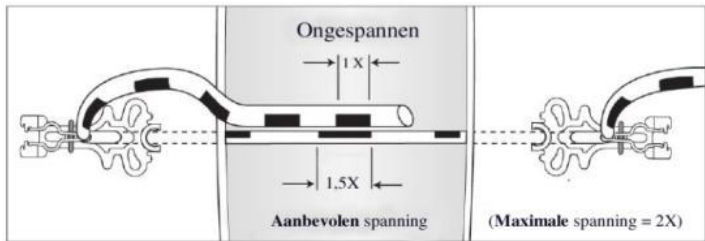
Plaats de ankers



Bevestig het elastomeer

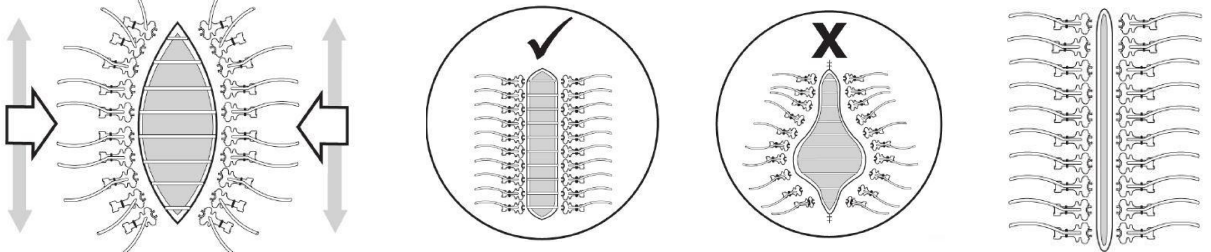


Trek de elastomeren strak



Verzorging na plaatsing

Trek de wond strak



Kritieke punten

- Het therapeutisch voordeel wordt gevormd door de cumulatieve reductiekracht die door alle elastomeren tezamen wordt uitgeoefend.
- Als een afzonderlijke elastomeer te strak wordt aangetrokken, veroorzaakt dit onnodig gelokaliseerd trauma wat resulteert in falen van het anker in kwestie, waarbij de resterende ankers zwaarder worden belast en een domino-effect resulteren, waardoor een compleet falen van het systeem kan ontstaan.
- Een wondbeweging van meerdere centimeters na ademcycli of lichaamsbeweging is normaal bij dynamisch te sluiten wonden, en vormt een indicatie van de juiste algehele spanning. De beweging wordt minder naarmate de wond zich verder sluit.
- Plaats geen restrictieve hulpmiddelen (met name buikbanden of stockinettes) boven op het systeem, omdat dit het therapeutisch effect vermindert en traumatische druk op de huid kan doen ontstaan.
- Zet de uiteinden van de elastomeren niet voorbij de gleuf in een anker vast, en leg er geen knopen in.



Instruções de Utilização

Conjunto de Encerramento Cirúrgico da Pele ABRA®

O Conjunto Cirúrgico da Pele foi concebido para encerrar defeitos na pele com um máximo de 20 cm de comprimento com uma força média a elevada.

Indicações

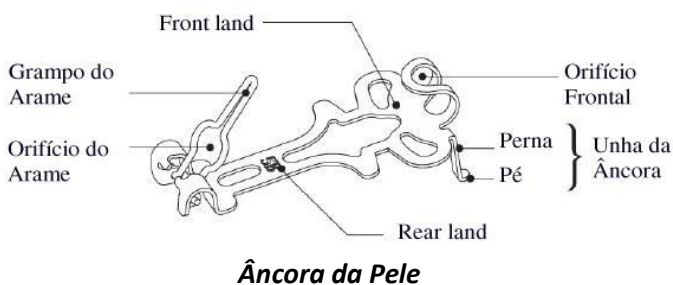
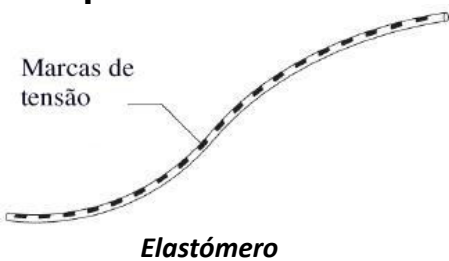
Os Sistemas Dinâmicos de Encerramento de Feridas são indicados no controlo, redução ou encerramento de defeitos dos tecidos moles retraídos.

Advertências

Não pode permanecer posicionado por mais de 29 dias.

Produto de utilização única, não devendo ser reutilizado em virtude de afetar o desempenho, a contaminação cruzada e o risco de infeção.

Perspetiva



Preparação do Leito da Ferida

Se a ferida for recente e os bordos móveis, saltar este passo. Caso contrário:

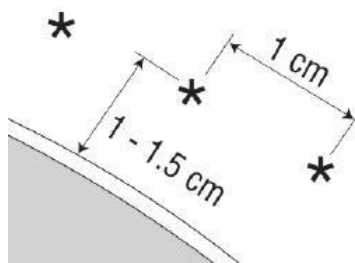
- Excisar os bordos invertidos da ferida.
- Remover todo o tecido de granulação.
- Escavar os bordos da ferida em 2 cm.

Instalação

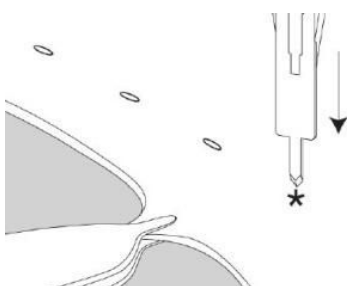
Obter Instrumentos



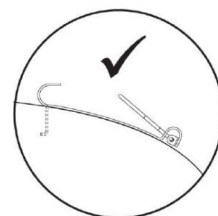
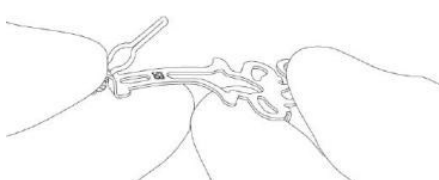
Marcar a Pele



Fazer Orifícios para a Unha da Âncora



Dar Forma às Âncoras

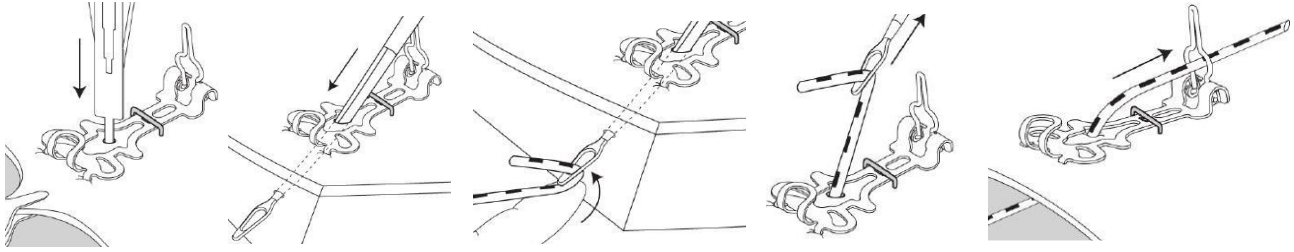




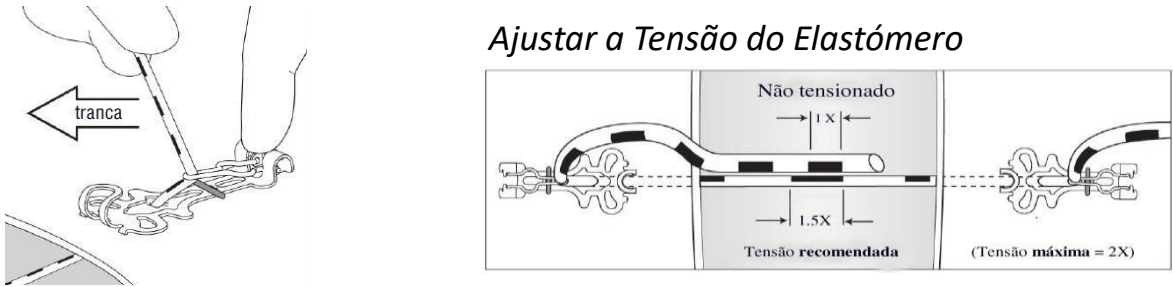
Colocar Âncoras



Fixar o Elastômero

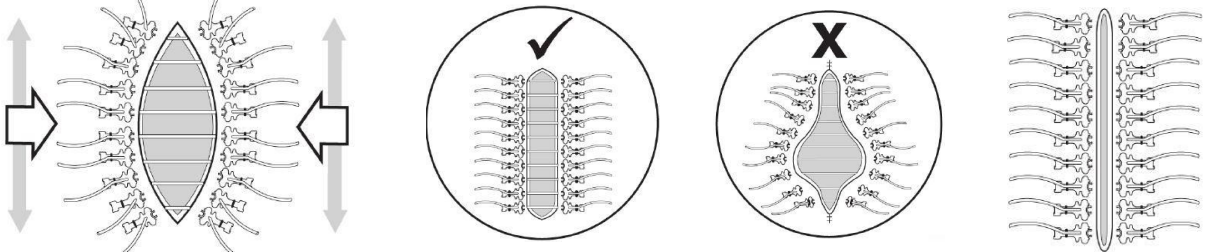


Ajustar a Tensão do Elastômero



Cuidados Pós-Instalação

Aplicar Tensão na Ferida



Pontos Essenciais

- O benefício terapêutico deriva da força de redução cumulativa aplicada por todos os Elastômeros.
- O tensionamento excessivo de um Elastômero individual resultará em trauma localizado desnecessário e levará à falha da Âncora individual, transferindo deste modo carga adicional para as Âncoras remanescentes e gerando uma cascata de eventos conduzindo à falha do Sistema.
- O movimento de vários centímetros da ferida após os ciclos respiratórios ou o movimento corporal é normal com feridas encerradas dinamicamente e indicativo de uma tensão total correta. O movimento diminuir-se-á à medida que a ferida se aproxime do encerramento.
- Não colocar nenhum dispositivo restritivo sobre o Sistema - sobretudo uma ligadura abdominal ou meia de compressão - uma vez que este irá limitar o efeito terapêutico e pode gerar pressões traumáticas na pele.
- Não prender ou atar a ponta do Elastômero atrás do grampo de qualquer Âncora.



Bruksanvisning

ABRA® kirurgisk hudförslutningsatts

Den kirurgiska hudsatsen är utformad för att försluta huddefekter som är upp till 20 cm långa med medelhög till hög styrka.

Indikationer

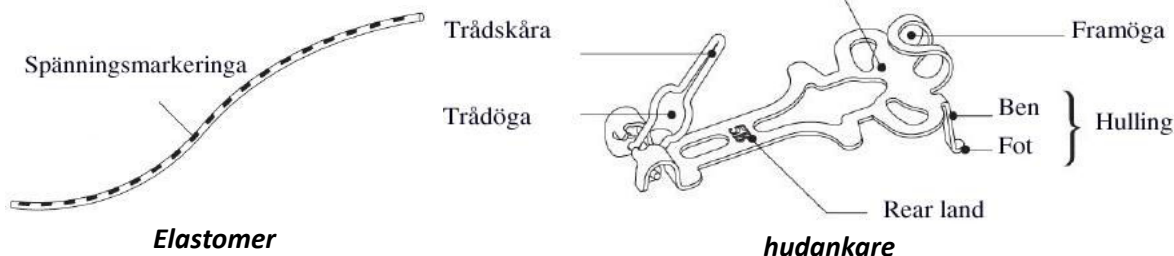
Dynamiska sårförslutningssystem indiceras för att kontrollera, minska eller försluta indragna mjukvävnadsdefekter.

Varningar

Får inte sitta kvar i mer än 29 dagar.

Engångsbruk produkt, får ej omanvändas pga effekt på prestanda, kross kontaminering och infektionsrisk.

Översikt



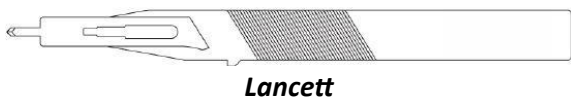
Förberedelse av hudbädden

Om såret är nytt och sårkanterna är rörliga kan steget hoppas över. Annars:

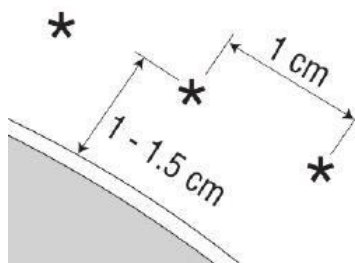
- Excidera indragna sårkanter.
- Avlägsna all granulationsvävnad.
- Underminera sårkanterna med 2 cm.

Inläggning

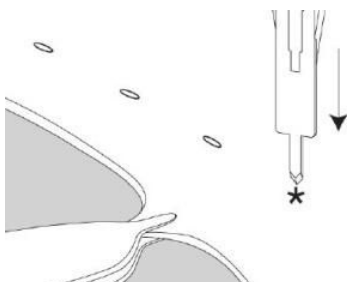
Ta fram instrument



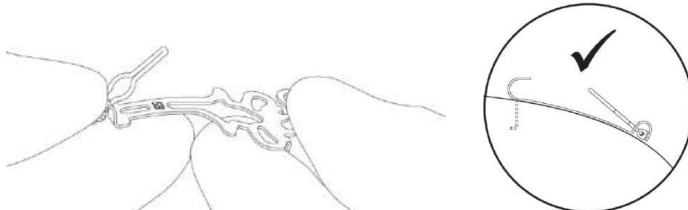
Markera på huden



Gör hullinghål

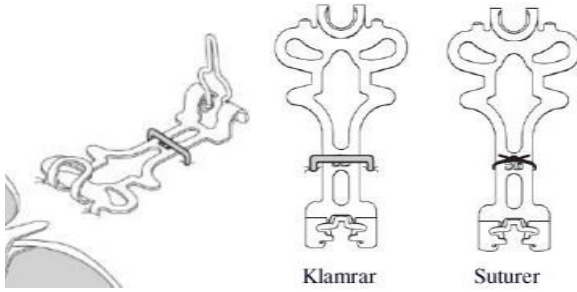
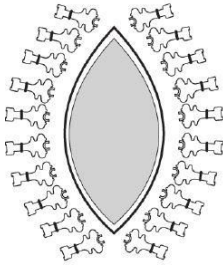


Konturera ankarna

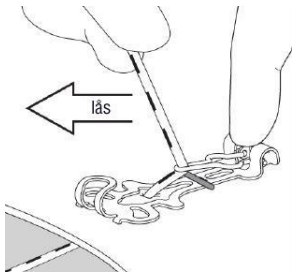
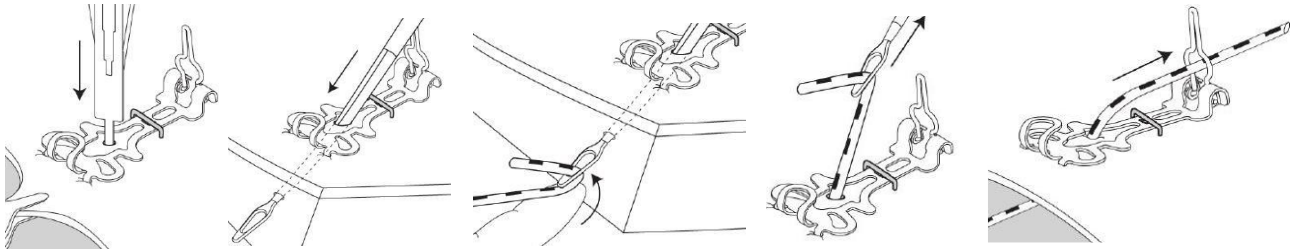




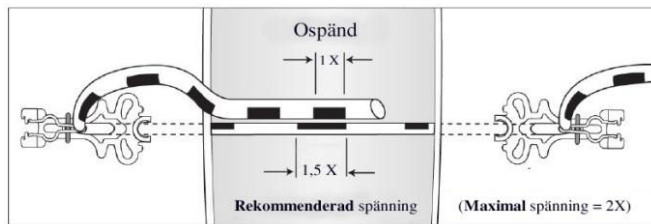
Placera ankarna



Fäst elastomerer

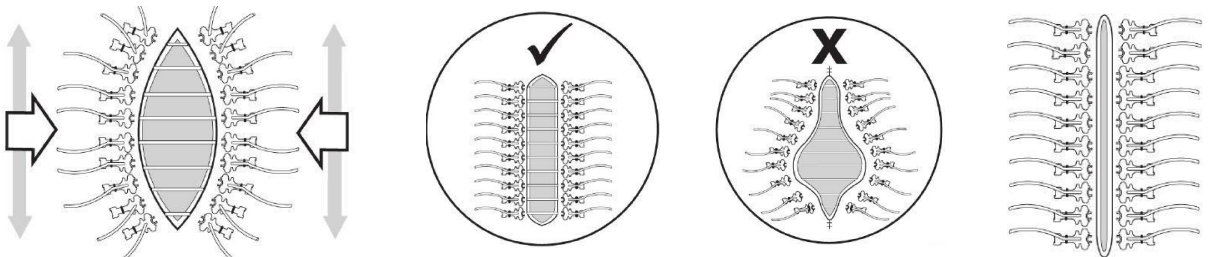


Justera spänningen på elastomererna



Omvårdnad efter inläggning

Spänn in såret



Kritiska punkter

- Den terapeutiska fördelen är den sammantaget minskade spänningsstyrkan som alla elastomerer åstadkommer.
- Överspänning av en enskild elastomer kommer att leda till onödiga lokala trauman vid enskilda ankare, vilket överför ytterligare styrka på de återstående ankarna och därmed skapar en vågrörelse som riskerar att störa hela systemet.
- Sår rörelser på flera centimeter på grund av respirationscykler eller kroppsrörelser när normalt vid dynamisk förslutning av sår, och tyder på korrekt total spänning. Rörelserna kommer att minska när såret närmar sig förslutning.
- Placera förslutande enheter ovanför systemet – särskilt inte stödförband eller tryckförband – eftersom det kommer att begränsa den terapeutiska effekten kan skapa traumatiserande tryck på huden.
- Fäst eller knyt inte ändarna på elastomererna utanför skåran på ankaret.



Οδηγίες χρήσης

Σετ χειρουργικής σύγκλεισης δέρματος ABRA®

Το σετ χειρουργικής σύγκλεισης δέρματος έχει σχεδιαστεί για τη σύγκλειση δερματικών ελλειμμάτων, μήκους έως 20 εκ. με μέτρια προς υψηλή δύναμη τάσης.

Ενδείξεις

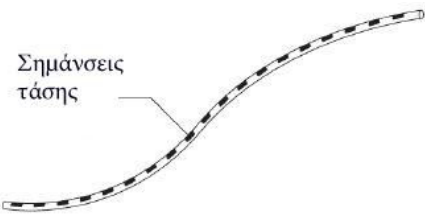
Τα συστήματα δυναμικής σύγκλεισης τραυμάτων ενδείκνυνται για χρήση στον έλεγχο, μείωση ή σύγκλειση ελλειμμάτων του μαλακού ιστού που έχει υποχωρήσει.

Προειδοποιήσεις

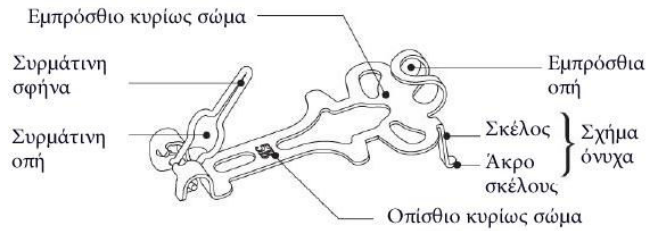
Δεν πρέπει να παραμένουν εφαρμοσμένες για περισσότερες από 29 ημέρες.

Το προϊόν μιας χρήσης δεν πρέπει να επαναχρησιμοποιείται εξαιτίας της επίδρασης στην απόδοση, της διασταυρούμενης μόλυνσης και του κινδύνου μόλυνσης.

Γενικά



Ελαστομερές



άγκιστρο δέρματος

Προετοιμασία κοίτης τραύματος

Εάν το τραύμα είναι φρέσκο και τα όρια μετακινήσιμα, παραλείψτε αυτό το βήμα. Διαφορετικά:

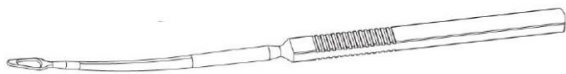
- Προβείτε σε εκτομή των ανεστραμμένων ορίων τραύματος.
- Αφαιρέστε όλο τον ιστό κοκκίωσης.
- Υποσκάψτε τις παρυφές του τραύματος κατά 2 εκ.

Τοποθέτηση

Λήψη εργαλείων

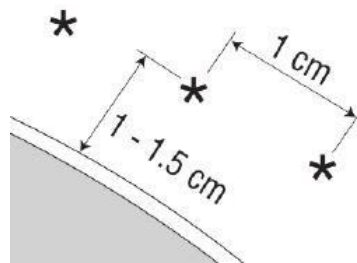


Νυστέρι

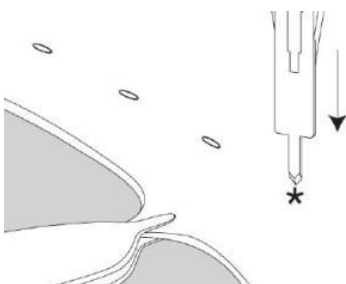


Εργαλείο εισαγωγής βρόχου

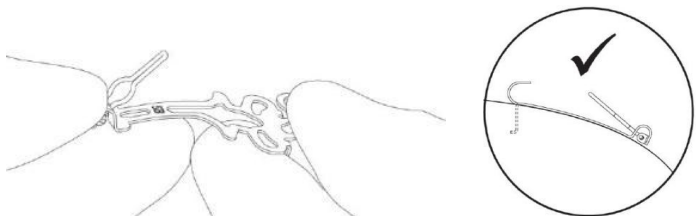
Επισήμανση δέρματος



Δημιουργία οπών σχήματος όνυχα

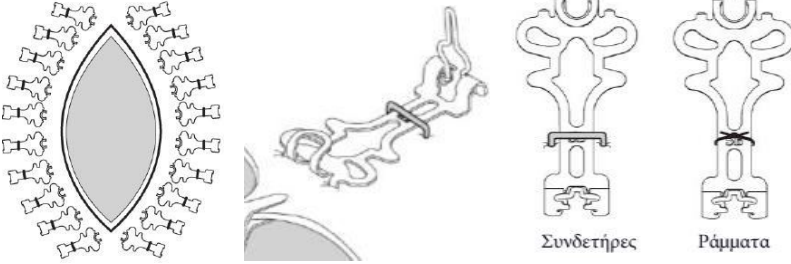


Διαμόρφωση περιγράμματος αγκίστρων

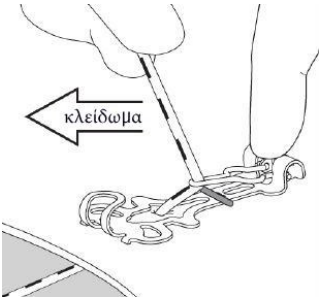
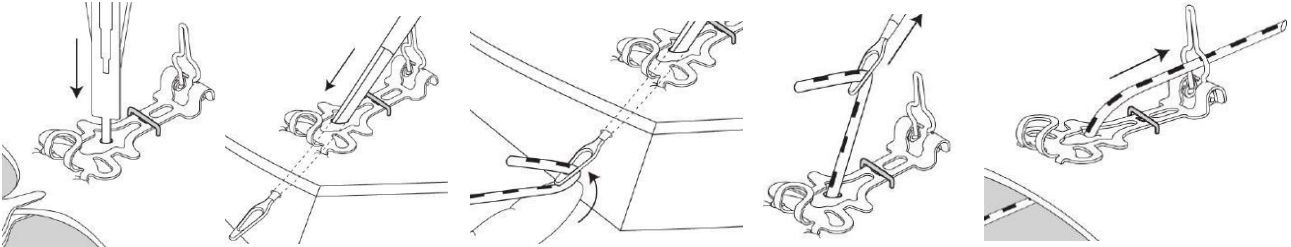




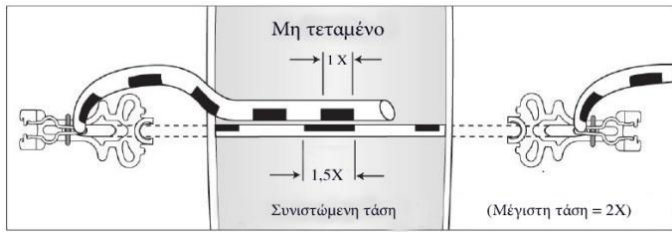
Τοποθέτηση αγκίστρων



Στερέωση ελαστομερούς

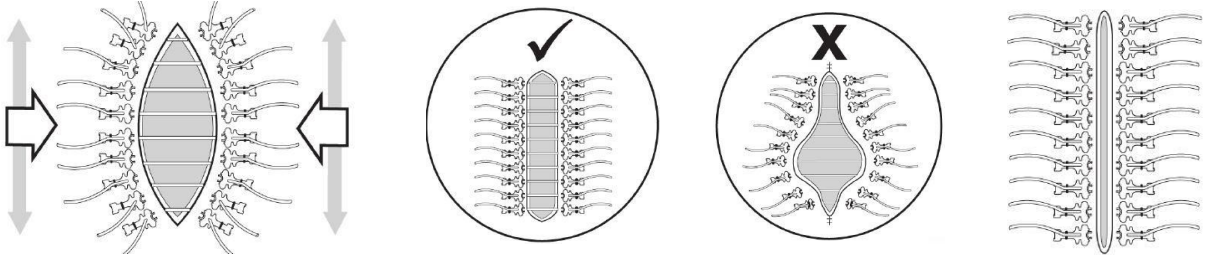


Προσαρμογή της τάσης του ελαστομερούς



Φροντίδα μετά την τοποθέτηση

Εφαρμογή τάσης στο τραύμα



Κρίσιμα σημεία

- Το θεραπευτικό όφελος προκύπτει από τη σωρευτική δύναμη μείωσης της τάσης που εφαρμόζεται από όλα τα ελαστομερή.
- Η υπερβολική τάση οποιουδήποτε μεμονωμένου ελαστομερούς θα οδηγήσει στην αποτυχία μεμονωμένου αγκίστρου λόγω περιττού εντοπισμένου τραυματισμού, μεταφέροντας, ως εκ τούτου, πρόσθετο φορτίο στα υπόλοιπα αγκίστρα, δημιουργώντας μια αλληλουχία αντιδράσεων με αποτέλεσμα μια γενική αστοχία του συστήματος.
- Η μετακίνηση του τραύματος κατά αρκετά εκατοστά μετά από κύκλους αναπνοής ή μετακίνηση του σώματος είναι φυσιολογική με τραύματα δυναμικής σύγκλισης και ενδεικτική της σωστής συνολικής τάσης. Η κίνηση θα μειωθεί, καθώς το τραύμα προσεγγίζει τη σύγκλιση.
- Μην τοποθετείτε οποιαδήποτε περιοριστική συσκευή πάνω στο σύστημα – ιδιαίτερα ζώνη σύσφιξης ή κάλτσες συμπίεσης – καθώς θα περιορίσει τις θεραπευτικές επιπτώσεις και μπορεί να δημιουργήσει τραυματικές πιέσεις στο δέρμα.
- Μην συγκρατείτε και μην δένετε σε κόμπο το άκρο του ελαστομερούς πίσω από τη σφήνα οποιουδήποτε αγκίστρου.