stryker

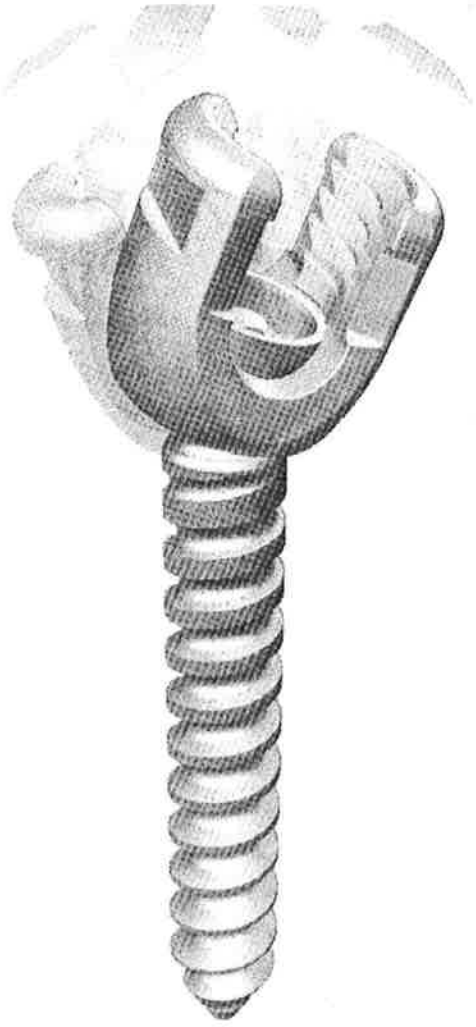
Columna

Sistema de Columna Xia®

Técnica Quirúrgica

Soluciones para Deformidades

Introducción



Importante: Los implantes e instrumentos Xia están diseñados y probados para ser utilizados únicamente con el Sistema de columna Xia.
Esta técnica quirúrgica detalla los procedimientos recomendados para el uso de implantes e instrumentos del Sistema para columna Xia. Proporciona una guía a tener cuenta, no obstante, como con cualquier guía técnica, cada cirujano debe considerar las necesidades particulares de cada paciente y realizar los ajustes apropiados si es necesario.

Nota:
Esta técnica es sólo para fines orientativos. Existen distintas técnicas para la colocación de tornillos pediculares y, como con cualquier procedimiento quirúrgico, un cirujano debe estar adecuadamente capacitado para efectuar el procedimiento.

Agradecimientos - Introducción

La evolución del Sistema de columna Xia® es otra prueba más del compromiso de Stryker Spine - la división de Columna de Stryker- de responder a las necesidades de la comunidad de cirujanos de todo el mundo y de proporcionar implantes e instrumentos que aporten mejores soluciones quirúrgicas.

El nuevo Sistema de acero inoxidable Xia® de Stryker Spine fue desarrollado y construido sobre la base del Sistema de columna Xia®. Hemos mantenido la facilidad de uso, el mecanismo de cierre superior de la rosca de apoyo y la fuerza biomecánica del sistema Xia®, pero hemos incorporado nuevas características y modificamos el diseño para abordar mejor la patología de la deformidad y atender los pedidos de los cirujanos que prefieren un implante con un perfil aun más bajo.

Stryker Spine quisiera agradecer a los siguientes cirujanos por su participación en el desarrollo continuo del Sistema de columna Xia®:

Stephen Mendelson M.D., Pittsburgh, PA
Dr. Urs Von Deimling, Colonia, Alemania
Dr. AB Verbout, Utrecht, Holanda
Stephen Milliner M.D., Phoenix, AZ
Thomas Errico M.D., NY, NY
John Bendo M.D., NY, NY
Joe Dryer M.D., NY, NY
Dr. Yutaka Nohara, Koshigaya, Japón

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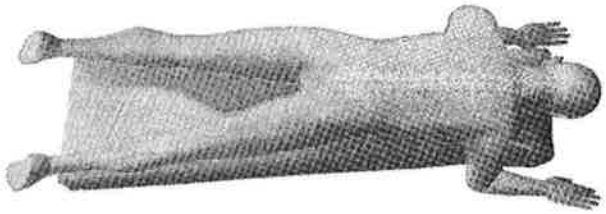
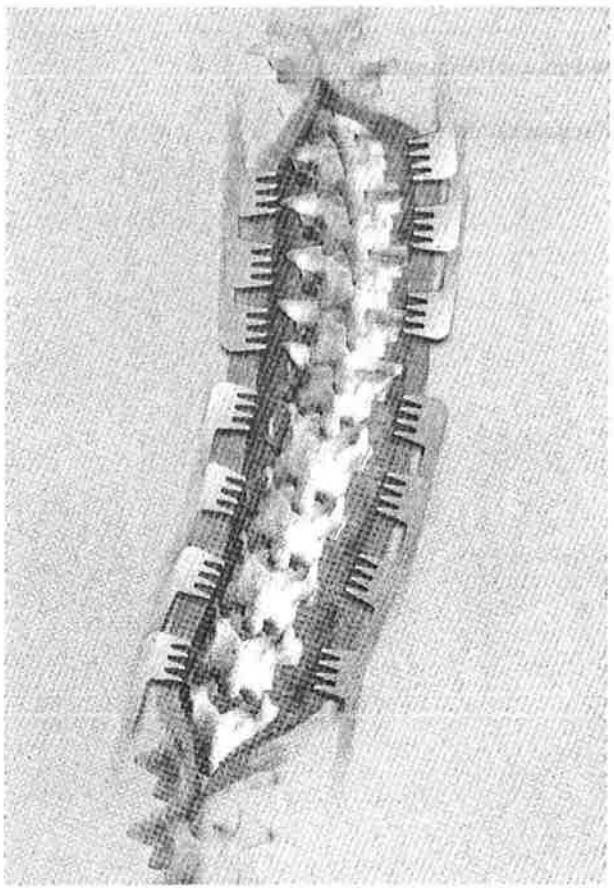
Técnica operatoria

A. Posición del paciente





Posición del paciente

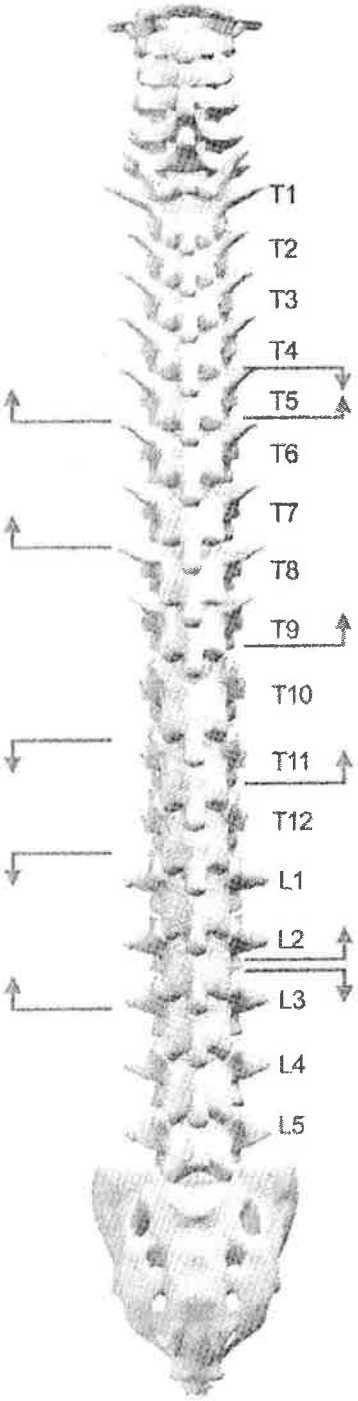
El diagnóstico de deformidad se basa en la historia clínica del paciente, los resultados de los exámenes físicos y la evaluación radiográfica preoperatoria.

Por lo general, el paciente se coloca boca abajo sobre una tabla espinal apropiada. Se toma la precaución de colocar almohadillas debajo de todas las prominencias óseas. El abdomen no debe estar comprimido a fin de facilitar el drenaje venoso.

Los niveles quirúrgicos pueden verificarse en forma clínica o radiográfica. Para garantizar una exposición adecuada, la incisión debe exceder apenas el largo de la fusión a realizar.

La planificación prequirúrgica permite determinar cuáles son los implantes más apropiados así como también su ubicación óptima.

A. Diseño de los ganchos

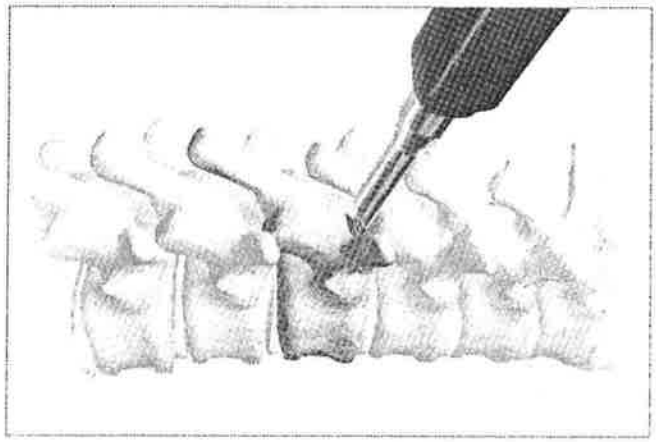


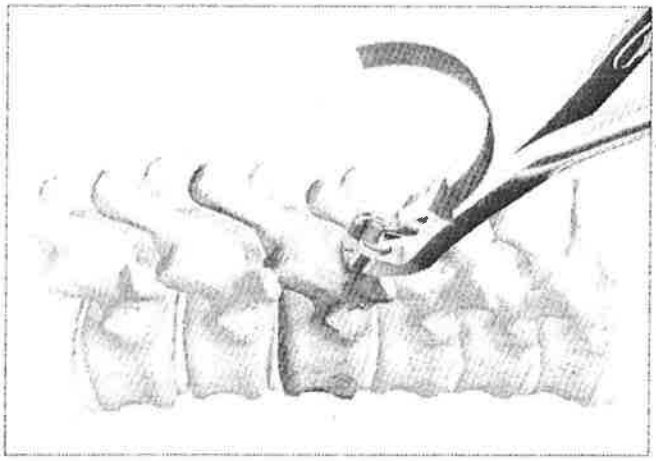
Preparación y colocación de los tornillos

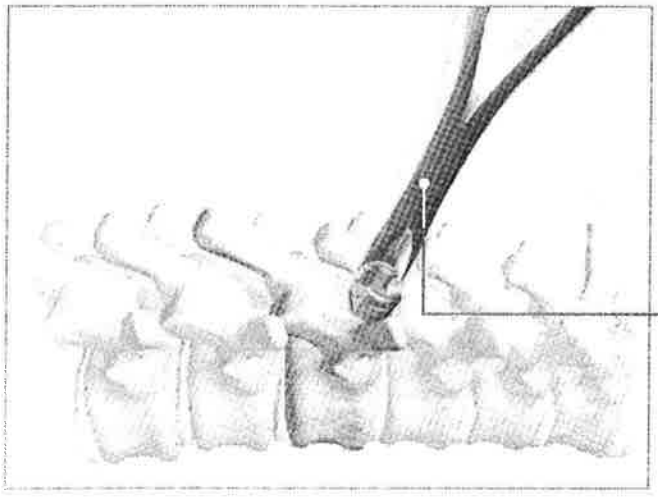
Una vez que se ha efectuado el corte apropiado y se han confirmado los niveles anatómicos mediante radiografías y puntos de referencia anatómicos, se identifican y preparan los sitios para los ganchos. Para elegir el gancho apropiado se tienen en cuenta varios factores: Anatomía del paciente, calidad ósea, técnica de corrección y fuerzas aplicadas. El cirujano cuenta con varias opciones para elegir un gancho relacionadas con el ancho de la hoja, la longitud de la garganta, la extensión del cuerpo y la forma del gancho. Los ganchos tienen tres tipos de hoja: hojas anchas, hojas estrechas y hojas pediculares bífidas. El cirujano debe elegir los ganchos que le permitirán llevar a cabo el procedimiento con el mayor éxito.

Los ganchos de compensación están disponibles en hojas anchas y estrechas. Pueden colocarse en los segmentos torácico o lumbar. Los conectores de compensación pueden ser útiles para alinear las conexiones de los ganchos.

B. Colocación de los ganchos







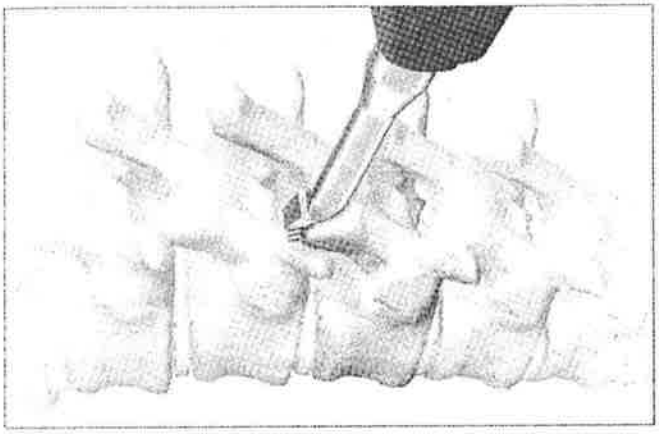
Ganchos supralaminares

Los ganchos supralaminares se colocan en dirección caudal. La hoja del gancho se apoya dentro del espacio epidural. Se recomienda un gancho con hoja estrecha con un tamaño de garganta que no permita un movimiento de desplazamiento sobre la lámina. El ligamento amarillo se separa de la lámina y se realiza una pequeña laminectomía. Se puede utilizar el Preparador de la lámina para calcular el tamaño apropiado del gancho.
Los ganchos e instrumentos deben introducirse en el canal espinal abierto con extremo cuidado. El Preparador de la lámina viene con hojas de dos anchos diferentes para que coincida de manera exacta con la anatomía del paciente.
Para elegir el gancho apropiado se debe tener en cuenta la anatomía del paciente. Una vez que se ha verificado que el sitio esté bien preparado, el gancho seleccionado para la lámina se carga en un Fórceps para ganchos.

Existen dos opciones posibles para preparar el sitio y colocar el gancho:
Opción 1: Se crea una ventana horizontal extrayendo el ligamento amarillo combinado con una osteotomía limitada del borde de la lámina. El tamaño de la ventana deberá ser lo suficientemente grande de modo que permita colocar la hoja del gancho. Luego, la hoja se gira hacia abajo 90° y se asienta sobre la lámina. Esta técnica ayudará a la estabilización del gancho, lo que puede facilitar la introducción de la barra.

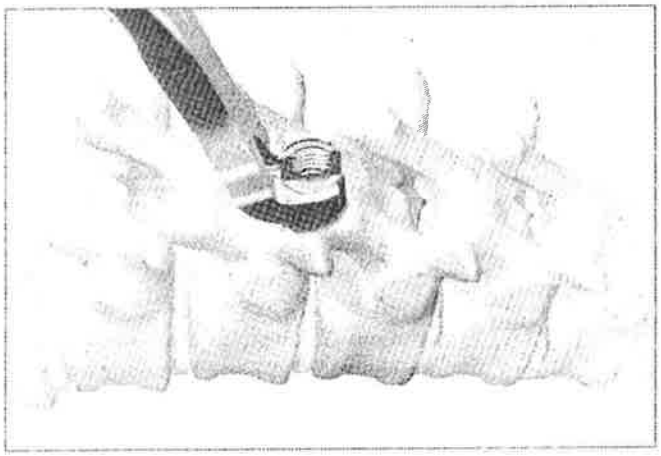
Opción 2: Se obtiene una ventana más cuadrada abriendo el ligamento amarillo conjuntamente con una laminectomía limitada.
Para seccionar el ligamento amarillo, puede utilizarse un Preparador laminar con sumo cuidado.
Una vez que se ha verificado que el sitio esté bien preparado, el gancho seleccionado para la lámina se carga en un Fórceps para ganchos recto o lateral.
El gancho se coloca con un movimiento de rotación hacia abajo de modo que la punta de la hoja abrace la superficie anterior de la lámina en todo momento. En ocasiones, es necesario quitar los bordes de la lámina para facilitar el acceso al canal.

B. Colocación de los ganchos

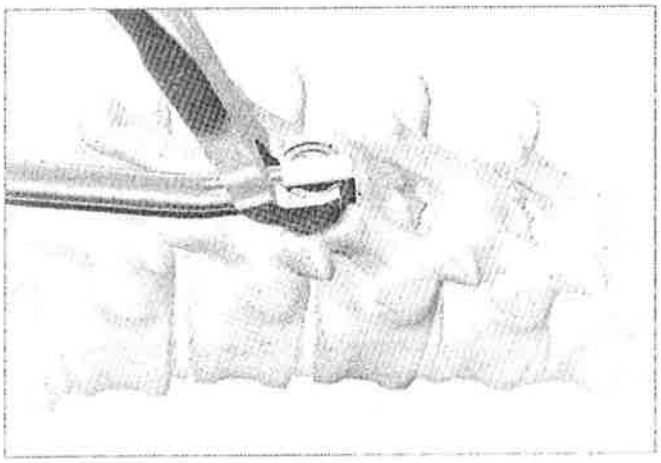


Ganchos infralaminares

Los ganchos infralaminares se colocan en dirección a la cabeza. El Preparador de la lámina se utiliza para separar el ligamento amarillo de la lámina inferior y preparar un trayecto para el gancho. La hoja se asentará entre la superficie anterior de la lámina y el ligamento amarillo y no en el espacio interdural.

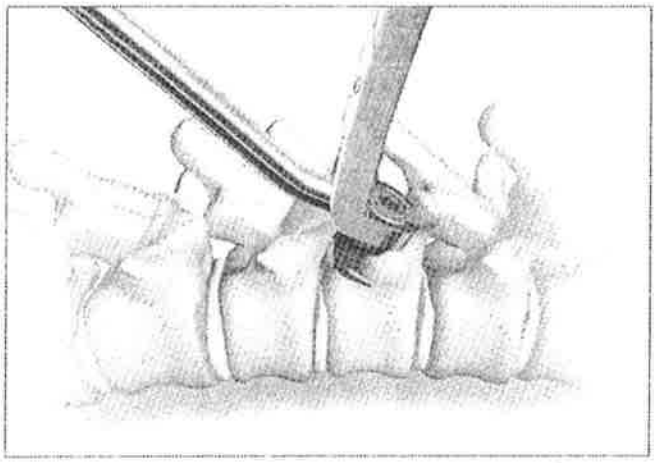


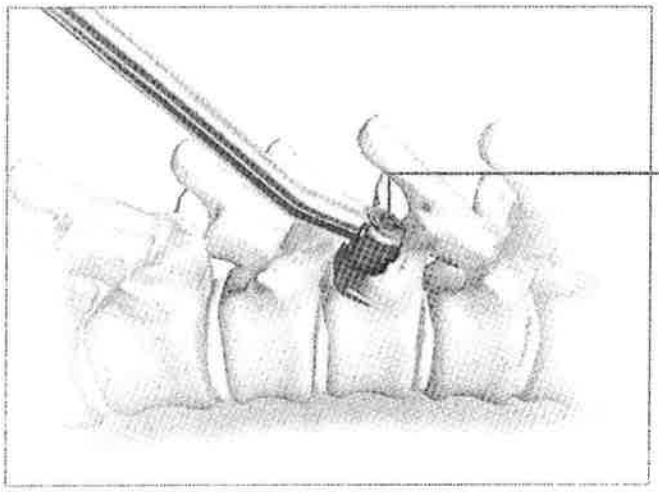
Puede seleccionarse una hoja ancha si la anatomía del paciente lo permite. Este gancho se carga en un Fórceps para ganchos y se coloca en el trayecto creado por el Preparador de la lámina.



El Impulsador para ganchos puede utilizarse conjuntamente con el Fórceps para ganchos para facilitar el asentamiento del gancho contra la lámina inferior.

B. Colocación de los ganchos





Ganchos pediculares

El gancho pedicular siempre se coloca en dirección a la cabeza y se recomienda para las vértebras T10 y superiores. Una osteotomía limitada (facetectomía) en la base de la carilla abre la carilla articular y expone el cartílago articular subyacente de la carilla superior de la vértebra caudal. El Preparador para ganchos pediculares se inserta en la carilla articular con extremo cuidado, apuntando ligeramente hacia el lateral de la línea media para identificar el pedículo. Una vez que se localiza el pedículo, puede utilizarse la hoja bífida del Preparador de pedículos para verificar que la horquilla se aplique correctamente en el pedículo. El preparador, correctamente enganchado en el pedículo, puede utilizarse para movilizar la vértebra lateralmente y así confirmar un ajuste confiable. Un elemento prominente indica la ubicación apropiada de la osteotomía final de modo que el gancho se asiente de manera uniforme sobre el pedículo y sobre la carilla.

El gancho pedicular se coloca una vez que se identifica claramente su sitio.

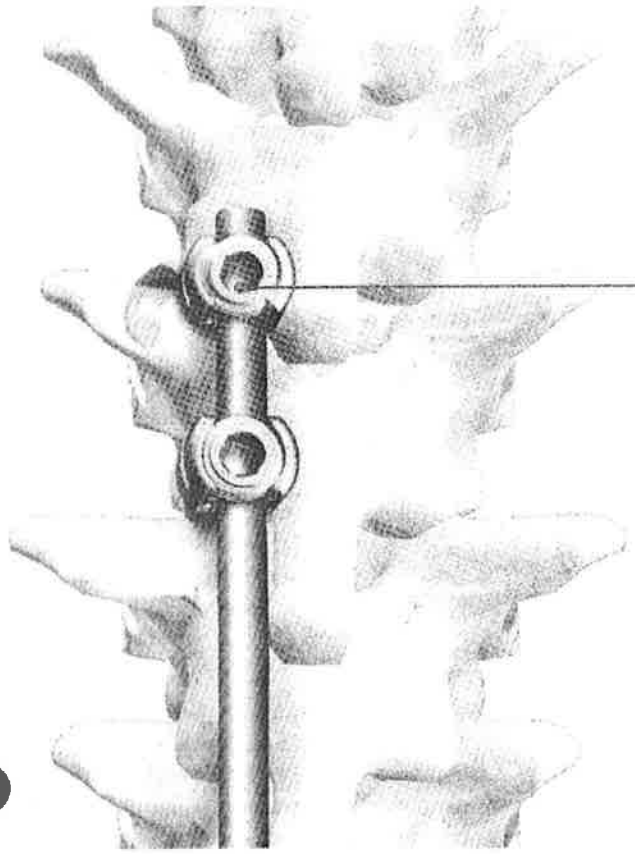
El Fórceps para ganchos sujeta el gancho con firmeza. El Impactador para ganchos se coloca en el gancho. El gancho se desliza hasta la posición deseada y luego, suavemente, se aprieta contra el pedículo. Luego, se lo desplaza de un lado a otro para asegurarse de que rodee al pedículo.

Esta combinación proporciona un nivel óptimo de fuerza y una guía para colocar el gancho en forma segura.

Método alternativo: El gancho se asegura temporalmente al Impactador para ganchos ajustando un Tornillo de cierre. El tornillo puede quitarse una vez que se ha ubicado el gancho.

Nota: Para facilitar la introducción del gancho pedicular, es posible que deba quitar la prominencia de la lámina caudal que se encuentra debajo del gancho.

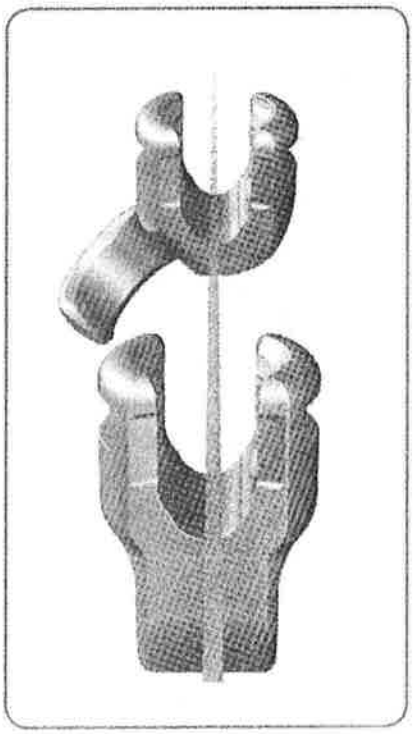
B. Colocación de los ganchos



Según la anatomía del paciente, puede seleccionarse un Gancho de proceso transverso Xia® o un gancho de lámina estándar. El gancho se carga en el Fórceps para ganchos. Luego, se coloca en el espacio creado con el Preparador de la lámina.

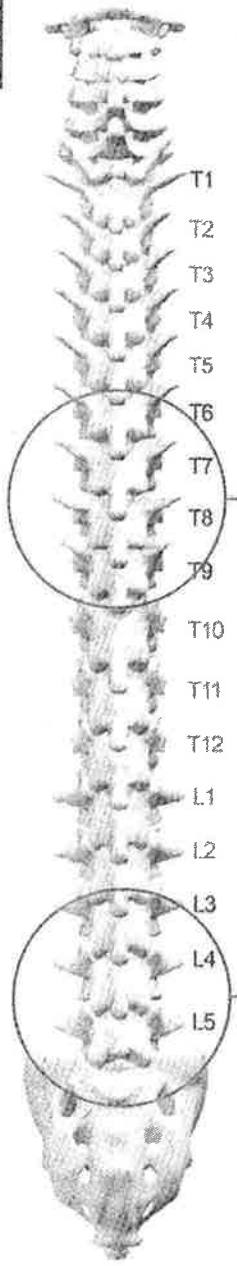
El gancho de proceso transverso puede colocarse en dirección caudal u orientado hacia la cabeza.

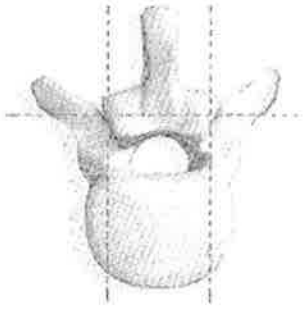
Los ganchos de proceso transverso colocados en dirección caudal a menudo constituyen la parte superior de la configuración de la garra pedicular transversa.
El Gancho de proceso transverso Xia® está diseñado para alinearse estrechamente con el gancho pedicular inferior a fin de ayudar a la angulación axial y permitir que el Tornillo de cierre pueda introducirse fácilmente.

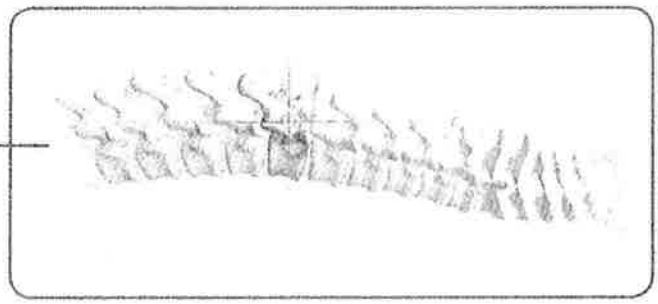


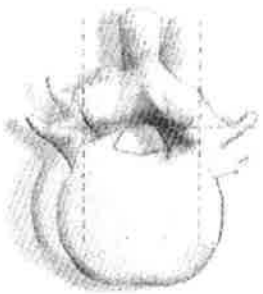
Nuevamente, el Preparador para ganchos de la lámina puede utilizarse para separar las superficies anterior y superior del proceso transverso a fin de generar espacio entre el aspecto anterior del proceso transverso y la cabeza de la costilla.

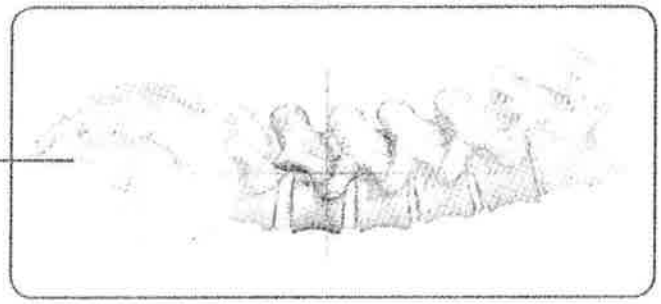
C. Colocación de los tornillos











Ingreso en los pedículos torácicos:

Los puntos de referencia generalmente se encuentran en la intersección de una línea vertical que atraviesa el centro de la parte convexa de cada proceso articular y una línea horizontal que pasa por el centro hasta el tercio superior de la base del proceso transverso. Generalmente, esta intersección se encuentra a 2mm por debajo del borde del cartílago articular y casi a nivel con la pequeña cresta ósea horizontal. Pueden utilizarse tomografías computarizadas (CT) para verificar cualquier variación anatómica.

Nota: Por lo general, un pedículo y la dirección de la perforación son globalmente perpendiculares al plano posterior de la vértebra (plano del proceso transverso).

Este es un punto importante a tener en cuenta, especialmente cuando se realizan maniobras instrumentales en las vértebras apicales, que, por lo general, son las más rotadas.

Ingreso en los pedículos lumbares:

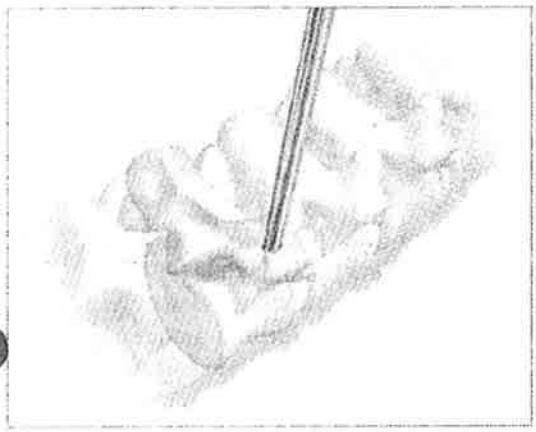
Los puntos de referencia se encuentran en la intersección de una línea vertical que atraviesa el espacio de la carilla articular y una línea horizontal que cruza el centro de la base del proceso transverso.

Estas dos líneas se cruzan en una pequeña cresta angulosa de hueso cortical que puede ser un punto de referencia confiable debido a que es extra-articular y no está afectada por deformidades osteoartríticas.

C. Colocación de los tornillos

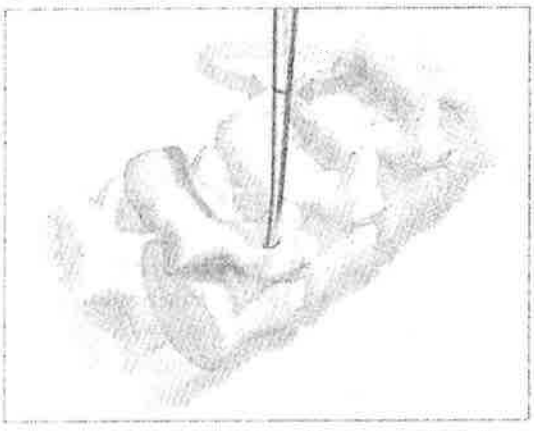
Preparación y colocación de los tornillos

La pequeña cresta cortical se elimina con una pinza gubia o fresa eléctrica para exponer el hueso esponjoso subyacente.

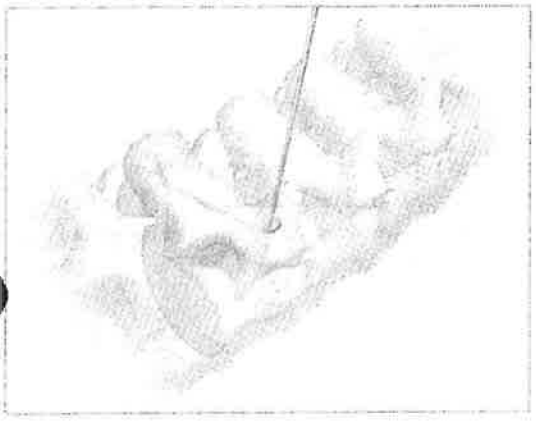


Identificación del ingreso de los pedículos

El punto de ingreso se prepara con el Punzón cuadrado (03807001), que no debe introducirse más de 10 mm.

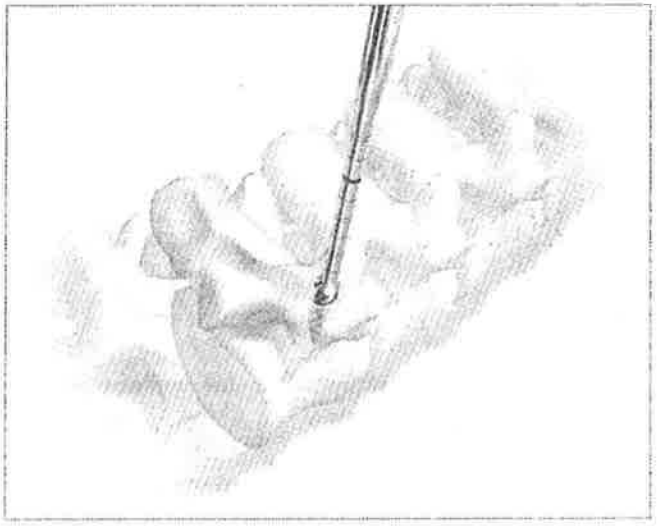


Luego, se abre el trayecto con la Sonda de aguja corta (03807024). La sonda debe tener contacto con el hueso en todo momento. La correcta inserción rotacional del instrumento permitirá que la sonda siga una trayectoria de menor resistencia sin atravesar las paredes del pedículo. En caso de que se perciba resistencia, el punto de ingreso y la trayectoria deberán evaluarse nuevamente. La Sonda pedicular se calibra y graba con láser con intervalos de 5 mm para ayudar a indicar la profundidad en la que se ha colocado y a determinar la longitud apropiada del tornillo.



El trayecto preparado se verifica con la Varilla sensible (03807003) a fin de controlar que no se hayan dañado las paredes del pedículo y que se perciba el hueso esponjoso en el extremo distal del trayecto. La Varilla sensible se calibra del mismo modo que la Sonda pedicular.

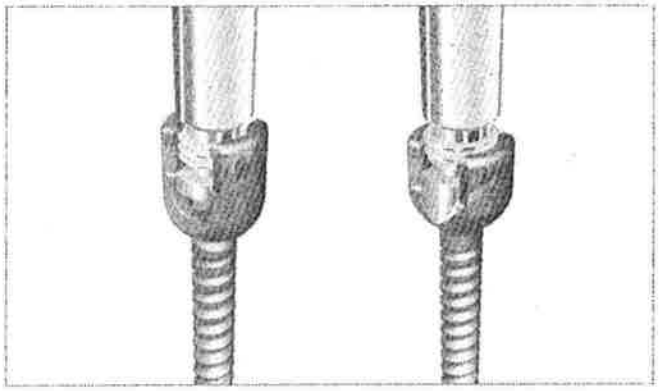
C. Colocación de los tornillos



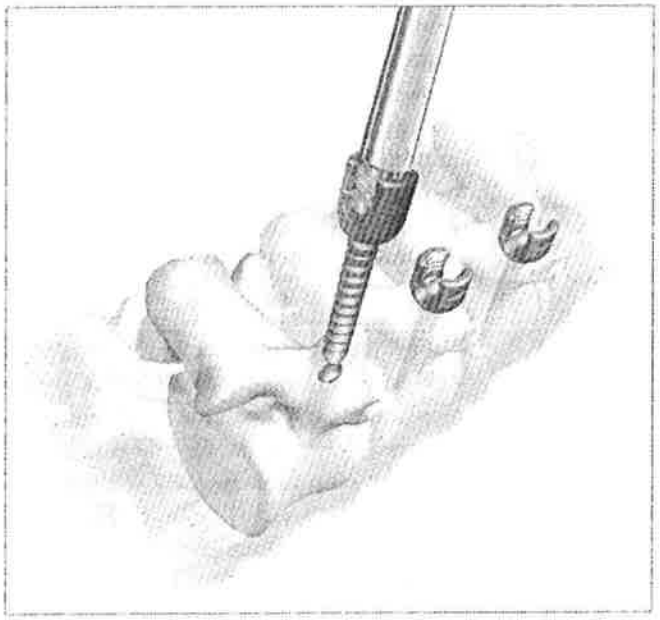
Preparación y colocación de los tornillos

Si el hueso es demasiado duro, debe utilizarse el macho de rosca apropiado para preparar el canal para el tornillo pedicular. Los machos de rosca son de 4,5 mm/5,5 mm (03807004) y 6,5 mm/7,5 mm (03807005). Se encuentran disponibles los machos de rosca modulares de 4,5; 5,5; 6,5 y 7,5 mm (48040154, 48040155, 48040156, 5,5 y 6,5 mm (48040165 y 48040166).

Los machos de rosca se calibran de la misma manera que la sonda y la varilla sensible.



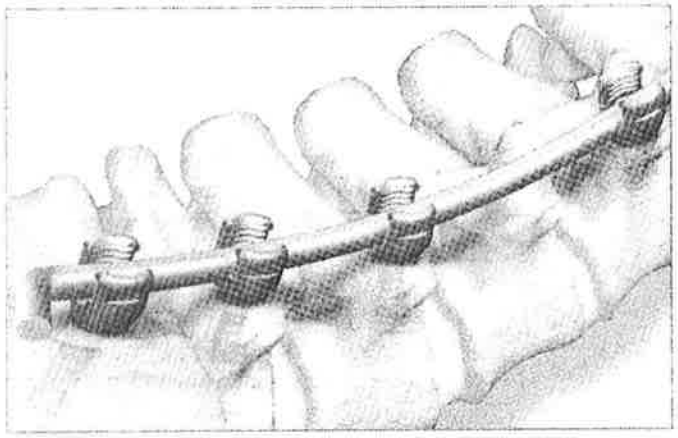
Los destornilladores poliaxial (48041310) y monoaxial (48041320) proporcionan una conexión muy rígida entre los tornillos poliaxiales y monoaxiales y el destornillador.



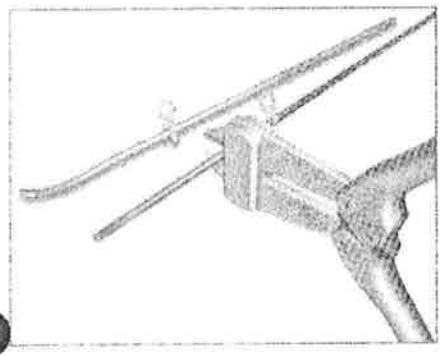
Una vez que se han preparado los trayectos pediculares y se ha determinado el diámetro y la longitud adecuados de los tornillos, se prepara el tornillo para su colocación.

Nota: Los tornillos poliaxiales pueden bloquearse en la colocación. Utilice el Insertor para desbloquear las cabezas antes de introducir la barra.

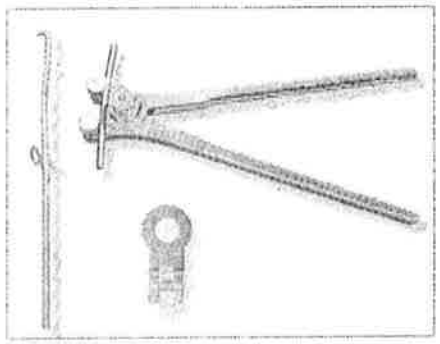
D. Contorneado de la barra



Una vez que se colocaron todos los tornillos, se corta la barra a una longitud apropiada de acuerdo con la construcción requerida. La Plantilla del Sistema para columna Xia® (03710620) se utiliza para determinar con exactitud la longitud apropiada de la barra.

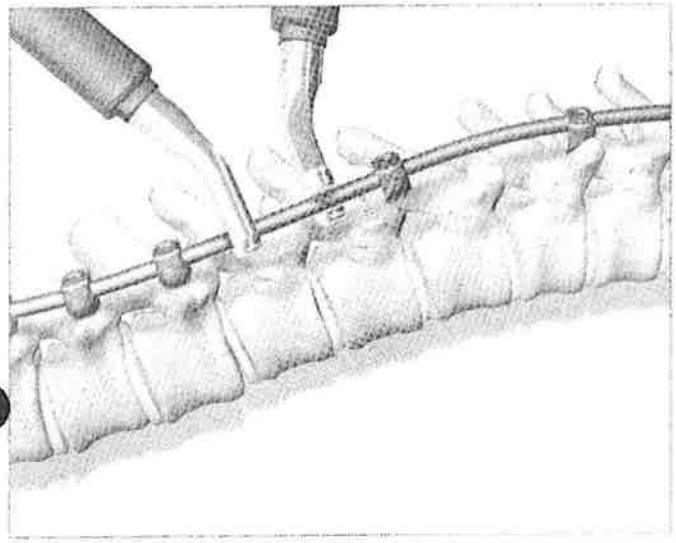


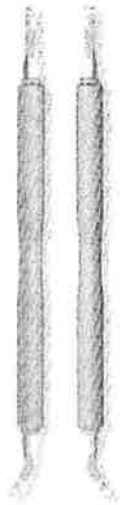
Utilice las barras precortadas apropiadas o corte una barra más larga con las Pinzas de corte (48047800). A También se encuentra disponible un cortador de barra para mesa (03808400). También se ofrecen barras rígidas con el Sistema Xia.



La barra se curva para adaptarse a los contornos de la columna deseados. El clip de orientación es útil para mantener la orientación espacial durante la curvatura.

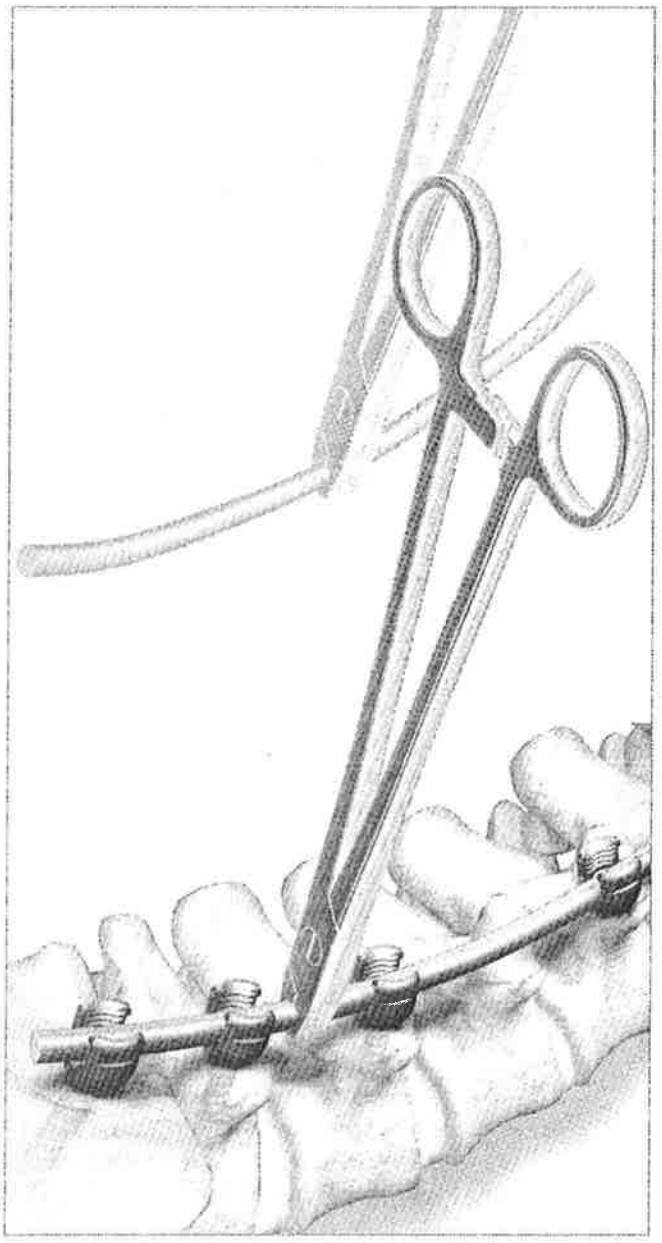
La curvatura puede realizarse con las Curvadoras francesas de Xia (03807010). Con el fin de contornear la barra, se deben realizar una serie de pequeños ajustes progresivos para curvarla gradualmente y garantizar una distribución uniforme de la tensión.





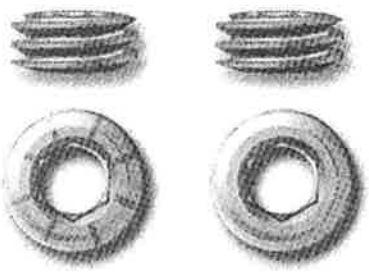
Los hierros de curvatura (48047011R/L) pueden utilizarse para realizar la curvatura in situ a fin de lograr maniobras finales de corrección progresivas. Se debe tener cuidado de no realizar curvas extremas, para evitar que se concentre la tensión y se produzcan muescas en la barra.

D. Contorneado de la barra



Colocación de la barra

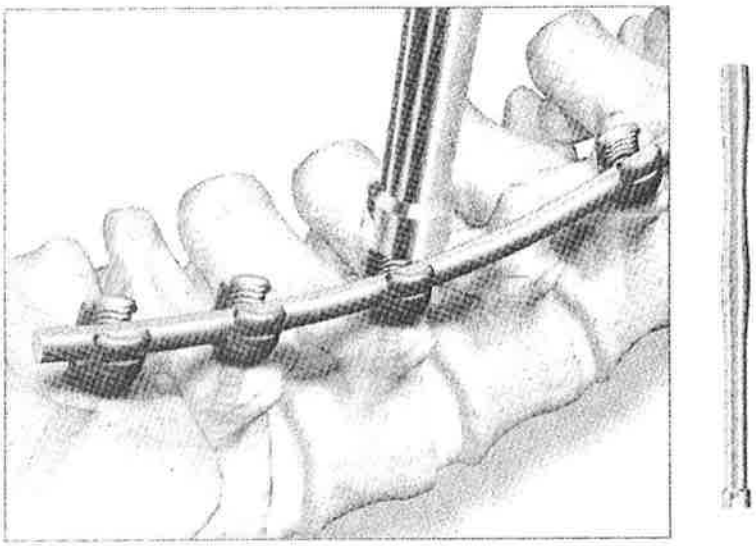
Una vez que la barra se curva para darle el contorno deseado, puede utilizarse el Fórceps para la colocación de la barra a fin de facilitar la introducción de la misma en las ranuras del implante. Esto puede realizarse en cualquier secuencia a criterio del cirujano. Puede ser útil comenzar el cierre en el lugar más sencillo. Es posible que esto facilite el asentamiento de la barra en los ganchos adyacentes.



Titanio Acero inoxidable

Nota: El Tornillo de cierre de titanio está grabado en láser para diferenciarlo claramente del Tornillo de cierre de acero inoxidable. Es importante no mezclar los metales Acero inoxidable y Titanio.

E. Conexión de la barra

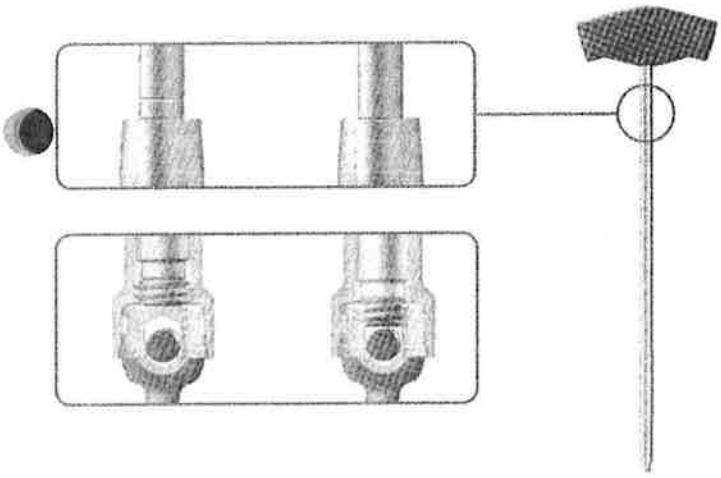


Insertor y tensor universal

El Sistema Xia® ofrece tres opciones para unir la barra a la columna:

Opción 1:

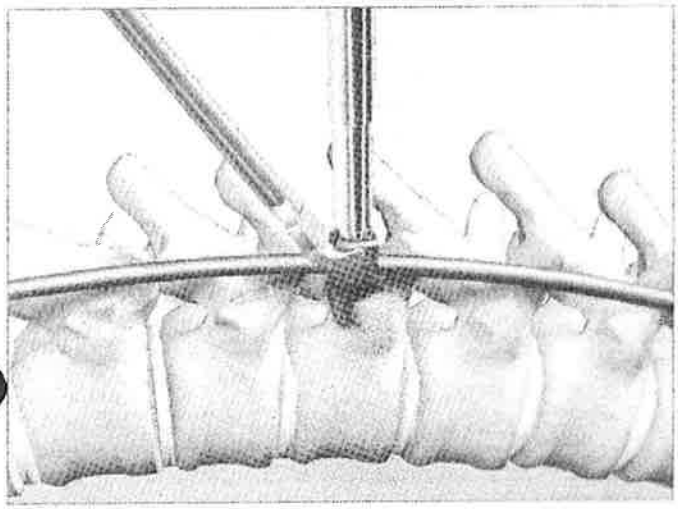
El Insertor (48047009) puede ayudarlo a alinear al Tensor universal, 5 mm (03807008) y el Tornillo de cierre con el implante.



Las dos líneas grabadas en el Tensor universal indican lo siguiente:

- Cuando la línea inferior está alineada con la parte superior del Insertor, el Tornillo de cierre está en la parte superior del implante.
- Cuando la línea superior está alineada con la parte superior del Insertor, el Tornillo de cierre está completamente introducido en el implante.

Nota: No realice el ajuste final del Tornillo de cierre con el Insertor colocado, de lo contrario será imposible retirarlo.



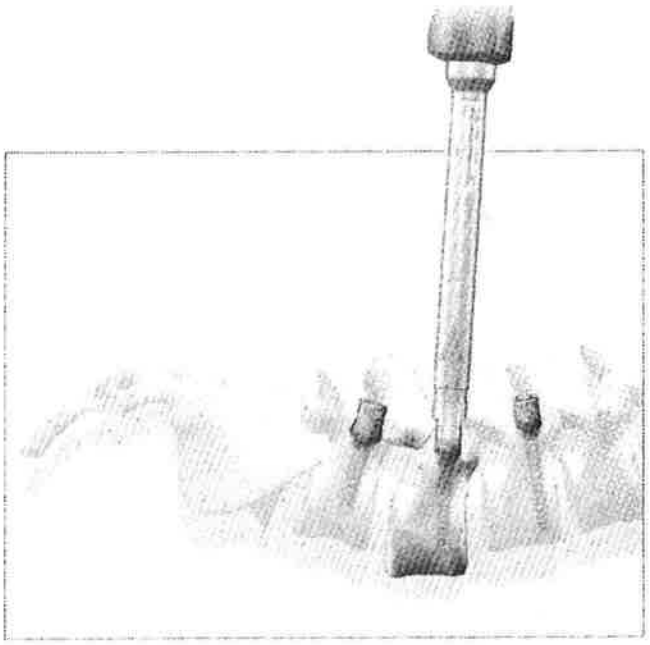
Opción 2:

Horquilla de la barra y tensor universal

La Horquilla de la barra (48047018) se utiliza cuando la barra sobresale ligeramente con respecto al asentamiento del implante.

La Horquilla de la barra se desliza fácilmente en las ranuras laterales sobre la cabeza del implante y gira hacia atrás. Esto eleva la barra hasta la cabeza del implante. El Tornillo de cierre se coloca con el Tensor universal cuando la barra está completamente asentada en la cabeza del implante.

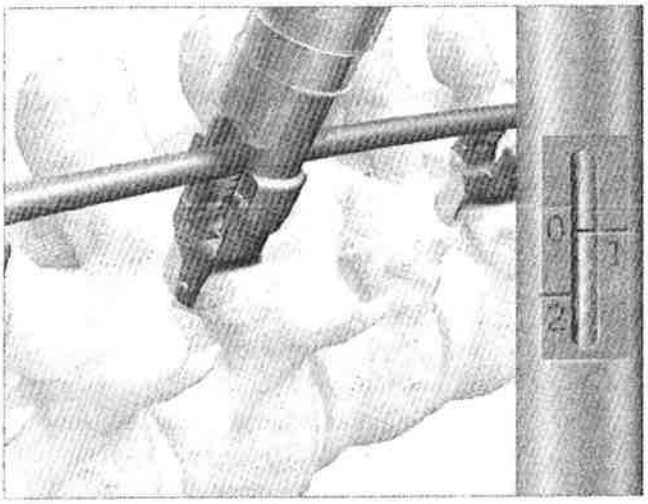
E. Conexión de la barra



Cómo utilizar el Persuasor

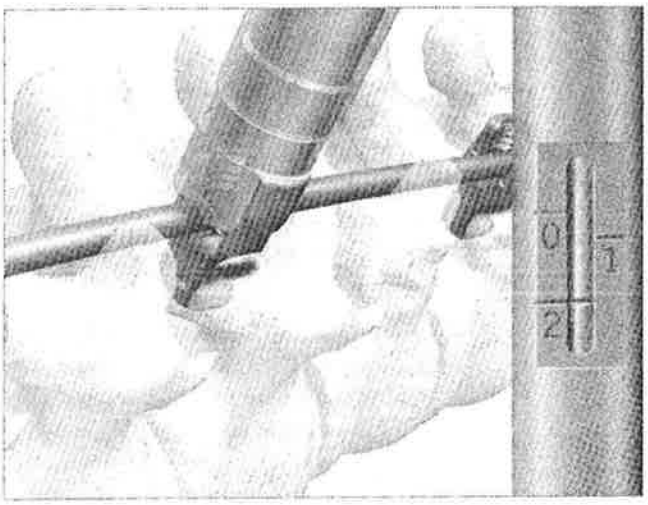
Opción 3:

El Persuasor se utiliza cuando se requiere fuerza adicional para llevar la barra hacia el implante.



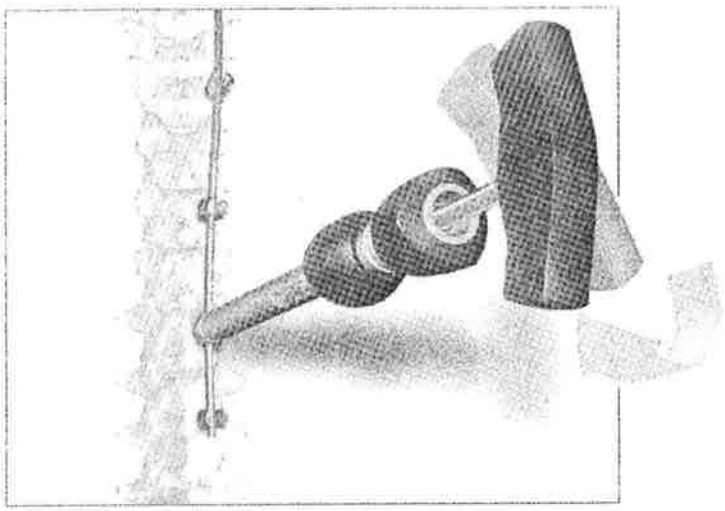
En la posición "0", conecte el Persuasor a la cabeza del implante.

Gire la cabeza del Persuasor hasta que la línea indicadora se desplace a la posición "1". El Persuasor ahora está fijado al implante. Desde esta posición, se puede empujar la barra dentro del tornillo.



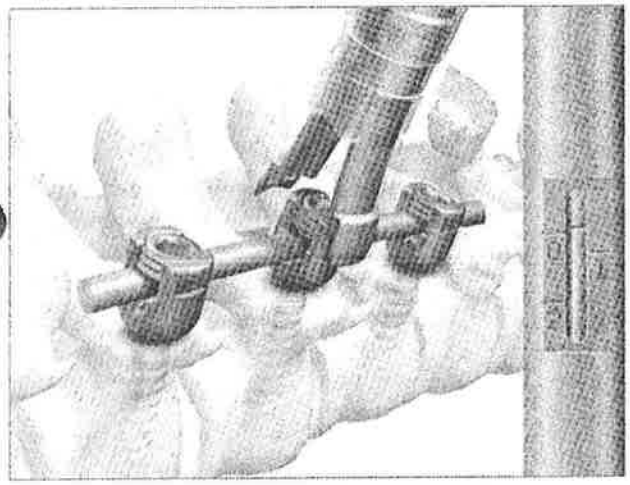
Gire la cabeza del Persuasor hasta que la línea indicadora se desplace a la posición "2". La barra ahora está completamente asentada permitiendo la colocación del Tornillo de cierre.

E. Conexión de la barra



Persuasor y tensor universal

Introduzca el Tornillo de cierre con el Tensor universal a través del Persuasor.

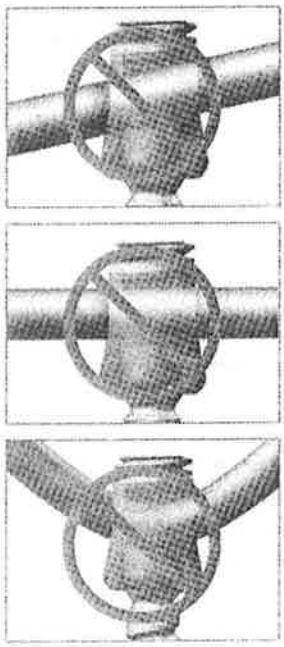


Para quitar el Persuasor, gire la cabeza del instrumento hacia atrás a la posición "0" y gire el instrumento completo.

Sugerencia 1: La barra no puede unirse a los tornillos o a los ganchos si tiene una curvatura aguda o abrupta en el punto de conexión.

Sugerencia 2: Si no puede alcanzarse la posición "2" al girar el Persuasor, no se podrá colocar el instrumento correctamente sobre el implante. Retírelo y comience el proceso de aplicación desde el principio.

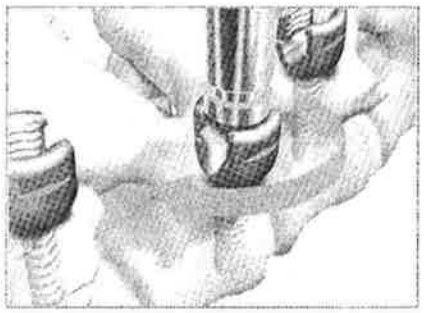
Sugerencia 3: El Persuasor no está diseñado para curvar la barra.

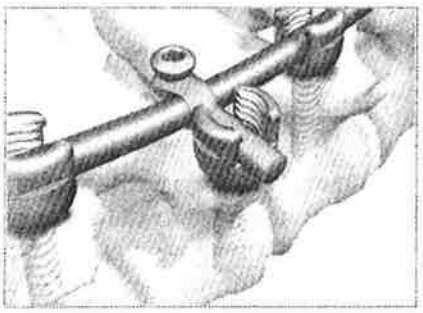


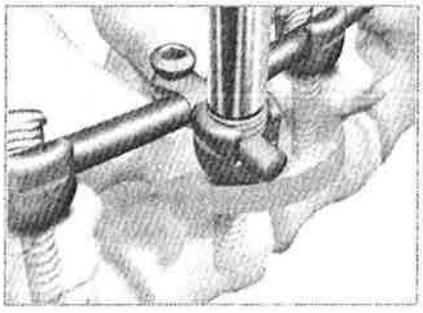
En caso de que la barra se fuerce hacia abajo mientras se ajusta el Tornillo de cierre, asegúrese de que la cabeza del tornillo esté bien sujetada. Esto ayudará a resistir las intensas fuerzas de reacción generadas por las maniobras de ajuste finales.

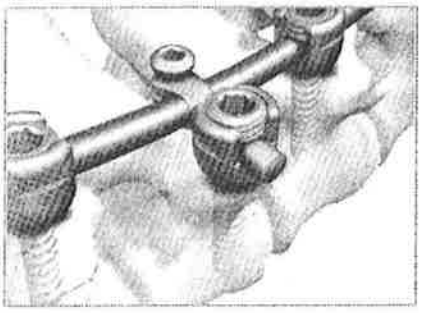
Se recomienda tomar precauciones adicionales cuando:
1) La barra no está colocada en forma horizontal en la cabeza del tornillo.
2) La barra está elevada en la cabeza del tornillo.
3) Una curva convexa o cóncava aguda está contorneada en la barra.

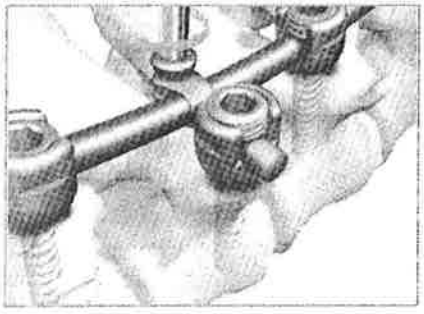
F. Conector lateral de compensación











Técnica operatoria

Conector lateral de compensación
El Conector de compensación permite una variabilidad media o lateral al conectar los tornillos a la barra. Estos conectores son útiles para alinear los tornillos con las conexiones de los ganchos.

La cabeza del tornillo gira 90º en dirección de las agujas del reloj.

El Conector de compensación se carga previamente en la barra con la orientación apropiada. Para obtener mayor estabilidad entre la barra y el Conector de compensación, éste puede ajustarse ligeramente en esta etapa.

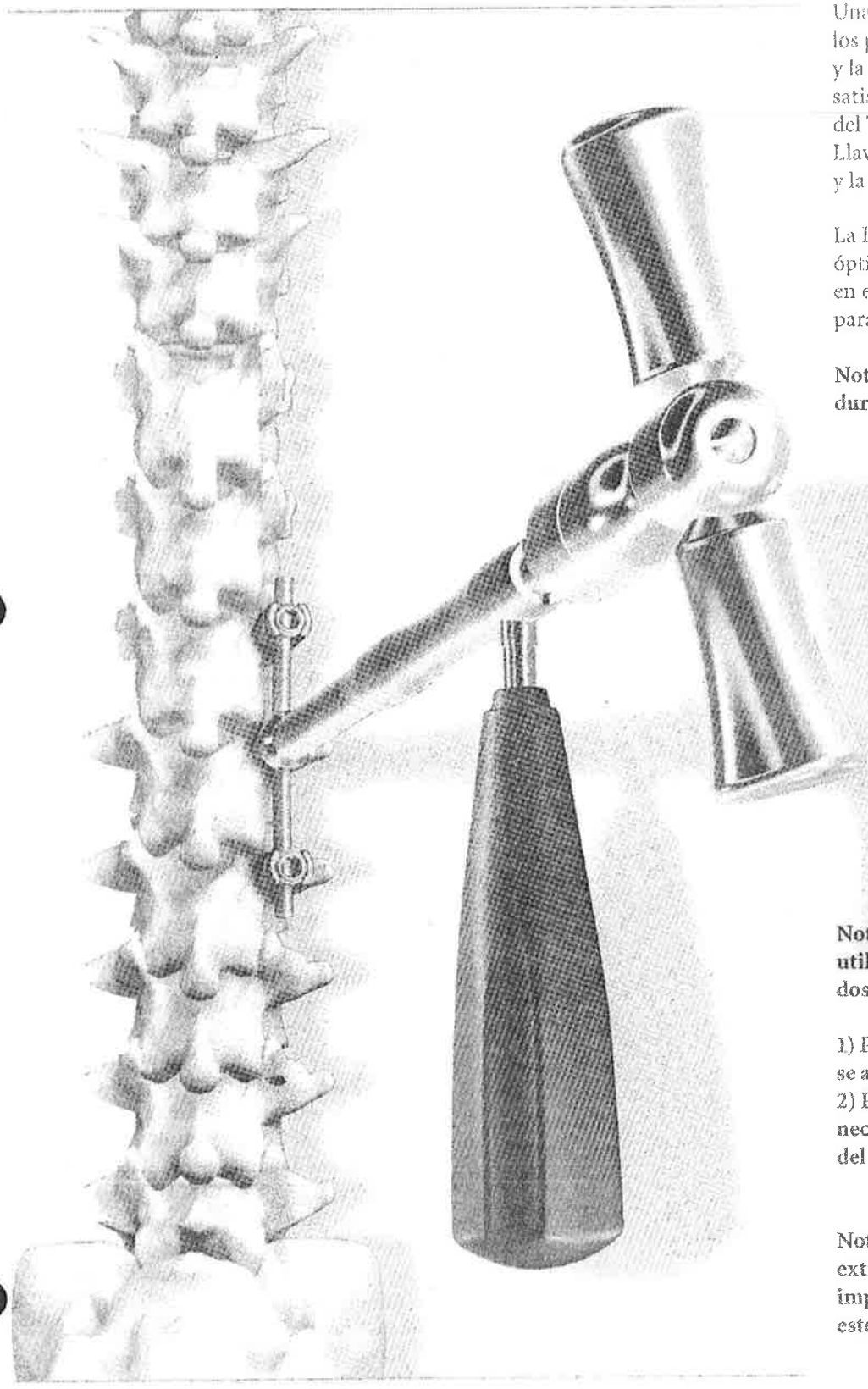
El Conector de compensación se coloca en la cabeza del tornillo. Se debe tener especial cuidado a fin de garantizar que el conector sobresalga al menos 1 mm del tornillo es pinal.

El Tornillo de cierre ahora se aplica utilizando el Tensor universal. La secuencia de tensión final para un tornillo pedicular se aplica al Tornillo de cierre cuando se utiliza en conjunto con el Conector de compensación.

Nota: El Conector de compensación se usa más fácilmente en combinación con el Tornillo poliaxial.

Nota: Si el Conector de compensación se utiliza con el Tornillo monoaxial, requiere una alineación exacta en el plano sagital de la cabeza del tornillo y la barra.

G. Ajuste final

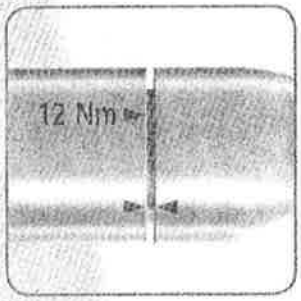


Cómo utilizar la llave de torsión

Una vez que se han llevado a cabo los procedimientos de corrección y la columna se fija en una posición satisfactoria, se realiza el ajuste final del Tornillo de cierre utilizando la Llave de anti-torsión (03807026) y la Llave de torsión (03807028).

La Llave de torsión indica la fuerza óptima que debe aplicarse al implante en el ajuste final. Alinee las dos flechas para lograr la torsión óptima de 12 Nm.

Nota: No se recomienda superar 12 Nm durante el ajuste final.

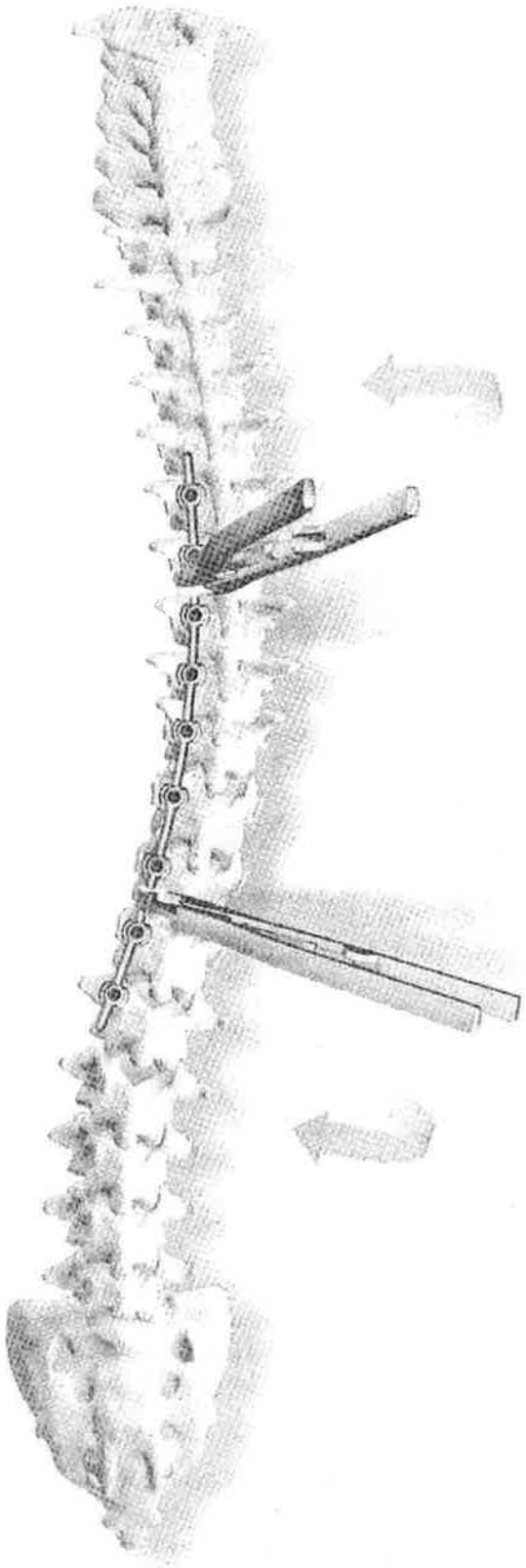


Nota: La Llave anti-torsión debe utilizarse en el ajuste final, cumple dos funciones importantes:

1) Permite que la Llave de torsión se alinee con el eje de ajuste.
2) Permite maximizar la torsión necesaria para bloquear el conjunto del implante.

Nota: Si la Llave anti-torsión no puede extraerse fácilmente de la cabeza del implante, es posible que la barra no esté completamente asentada.

H. Procedimientos de reducción



Corrección de la deformidad

Nuestro panel internacional de especialistas en escoliosis trabajó en el diseño del Sistema Xia® para ofrecer soluciones que se adapten a distintas filosofías quirúrgicas. La ventaja del Sistema Xia® consiste en que el cirujano no necesita apartarse de su filosofía quirúrgica.

La corrección de la deformidad puede lograrse utilizando uno de los cuatro procedimientos de reducción:

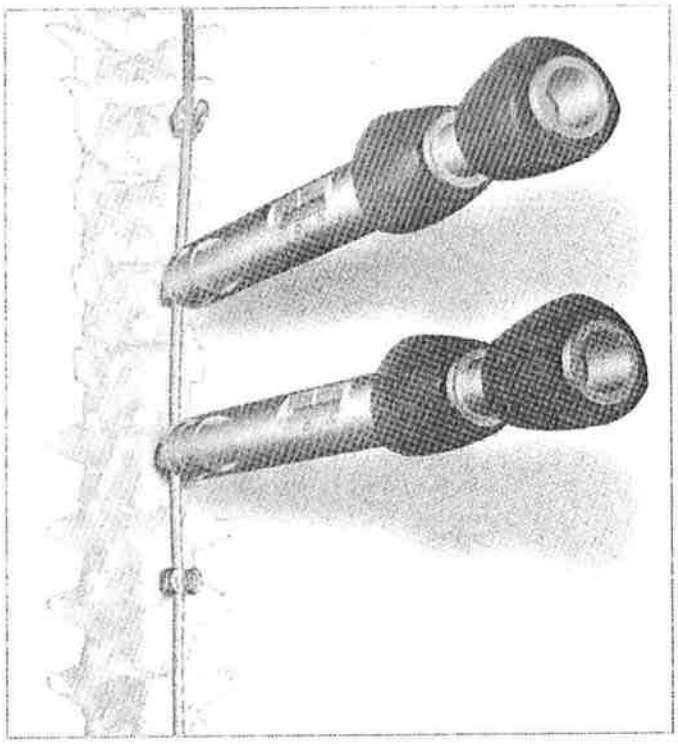
1. Derrotación de la barra
2. Desplazamiento
3. Distracción/Compresión
4. Curvatura in situ

Estas maniobras pueden utilizarse en forma independiente o en cualquier combinación a fin de facilitar la corrección óptima de las deformidades de columna.

Derrotación de la barra
Opción 1: Derrotación tradicional de la barra:

La maniobra de corrección rotacional puede aplicarse con la barra colocada en todos los implantes y los Tornillos de cierre colocados pero sin ajustar. La barra puede rotarse utilizando los dos Fórceps para rotación de barra. Asegúrese de que los Tornillos de cierre sólo estén ajustados provisoriamente para permitir un movimiento libre de la barra. El instrumental en forma de anillo en C puede utilizarse para mantener la posición de los ganchos mientras se realiza la maniobra de rotación de la barra. Generalmente, la barra se rota en un arco de 90° convirtiendo una deformidad escoliótica en la columna torácica en una cifosis sagital y una deformidad escoliótica lumbar en una lordosis lumbar. Una vez que la barra se ha girado completamente, se ajustan los Tornillos de cierre en forma provisoria. Se puede lograr la corrección de deformidades adicionales con más maniobras de distracción y compresión.

H. Procedimientos de reducción



Opción 2: Rotación de la barra para la aproximación del implante:

La técnica de rotación para la aproximación consiste en contornear la barra en el plano sagital en la forma deseada. La barra puede colocarse en los implantes hasta 90° fuera de la fase para minimizar la aproximación necesaria para el implante. La barra luego se gira, no con el fin de derrotar la columna, sino para colocar los implantes en la alineación apropiada. Entonces se realiza la corrección final empleando técnicas de distracción y compresión.

Desplazamiento

El desplazamiento puede lograrse empleando una técnica de cableado sublaminar o utilizando los instrumentos del persuasor.
Si emplea los instrumentos del persuasor para realizar el desplazamiento, utilice los dos persuasores incluidos en el juego. Estos persuasores generalmente se colocan en los extremos distal y proximal del ápice curvo. Debido a que la columna se desplaza cuidadosamente en estos puntos, se colocan los Tornillos de cierre y se aseguran los implantes. Los persuasores entonces se movilizan hacia el ápice de la curva hasta que finaliza el desplazamiento.

Distracción/Compresión

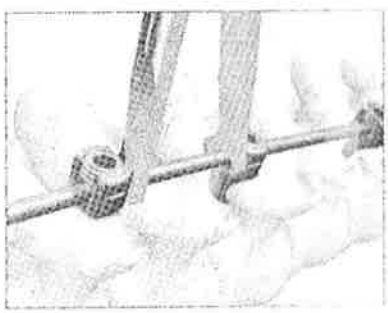
Las deformidades de la columna pueden sufrir un efecto mayor al crear una distracción en la concavidad de la deformidad y una compresión en la convexidad de la misma.

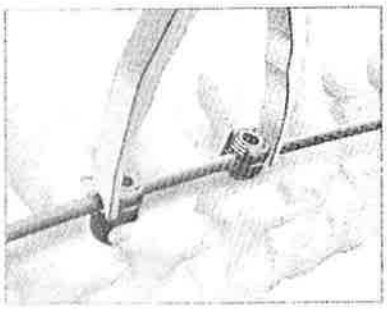
Nota: Una distracción posterior genera una cifosis en el plano sagital y una compresión produce una lordosis en el mismo plano. La compresión se logra con el Compresor y la distracción, con el Separador. Una vez que el montaje está en la posición deseada, bloquee los Tornillos de cierre con el Tensor universal.

Curvatura in situ

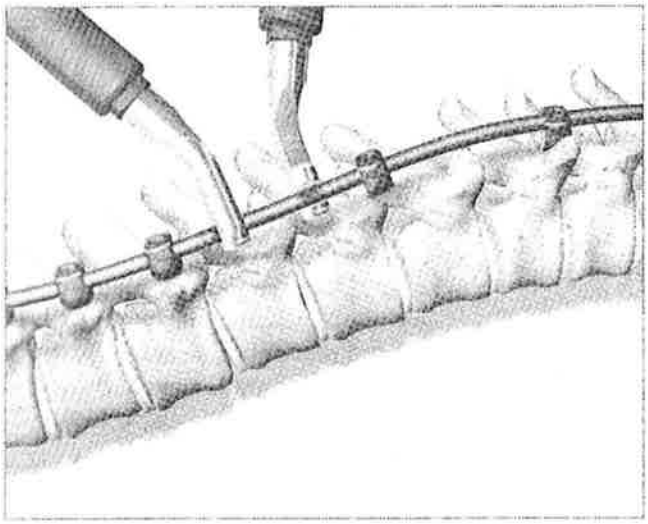
Se debe tener extremo cuidado de no sobrecargar la interfaz del implante óseo durante la curvatura in situ. Además, se debe tratar de no dejar hendiduras profundas en la barra, debido a que pueden debilitar el implante.

Asegúrese de que los Tornillos de cierre no están completamente ajustados durante las maniobras de rotación o el proceso de compresión y distracción.





H. Procedimientos de reducción

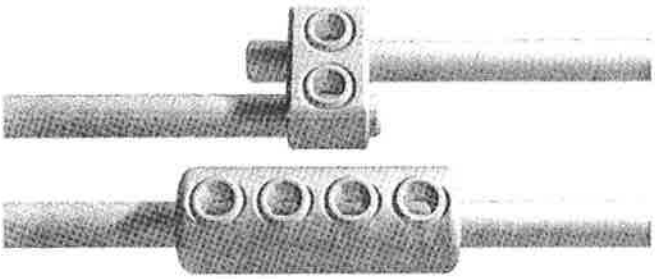


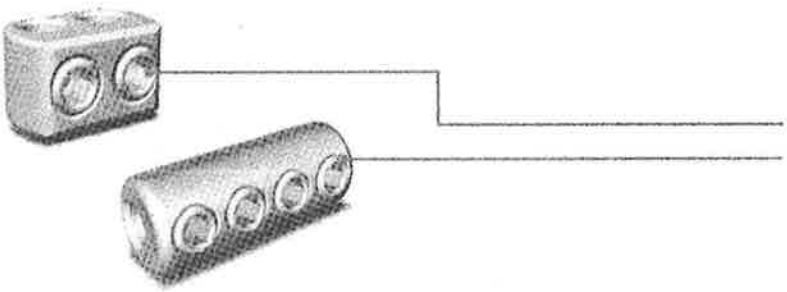
Corrección de la deformidad

Conexión de barra a barra
En ocasiones, se requiere una conexión de barra a barra. Existen dos opciones disponibles:

1. Conector dual
2. Conector axial

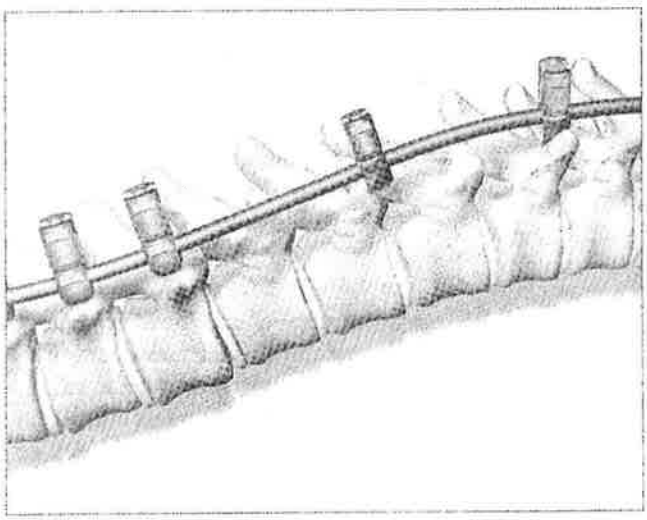
Para ajustar el Conector dual y el Conector axial se utiliza el Destornillador hexagonal de 3,5 mm.





1) Abrazadera dual de barra a barra
2) Abrazadera axial de barra a barra

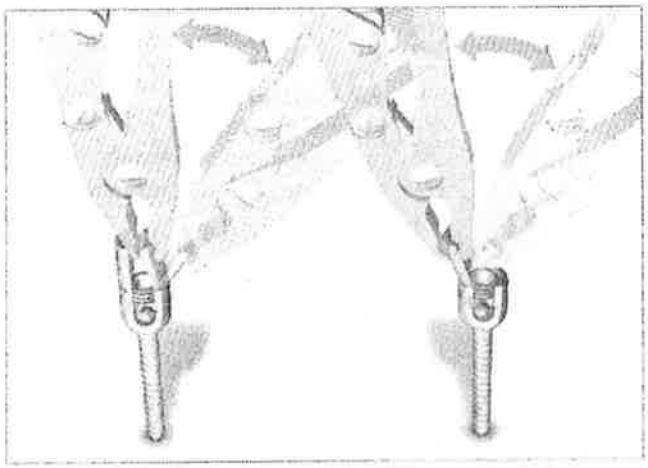
H. Procedimientos de reducción



Corrección de la deformidad

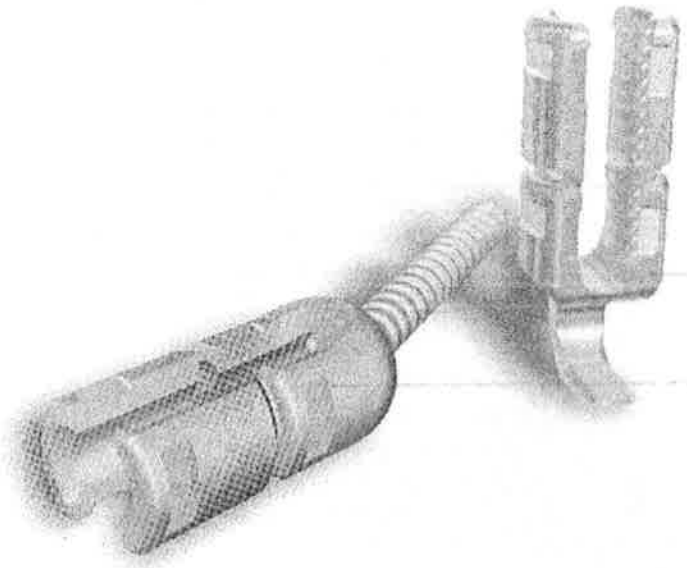
Los Tornillos y Ganchos de brazo largo Xia pueden utilizarse durante un procedimiento de reducción. Los Destornilladores monoaxial (48041340) y poliaxial (48041330) para reducción Xia se utilizan para colocar los Tornillos de brazo largo Xia en los pedículos.
Para manipular los Ganchos de brazo largo Xia se emplea el Fórceps para ganchos Xia (48041020).

El ajuste final se realizará después de colocar el mecanismo de cierre y separar los brazos.



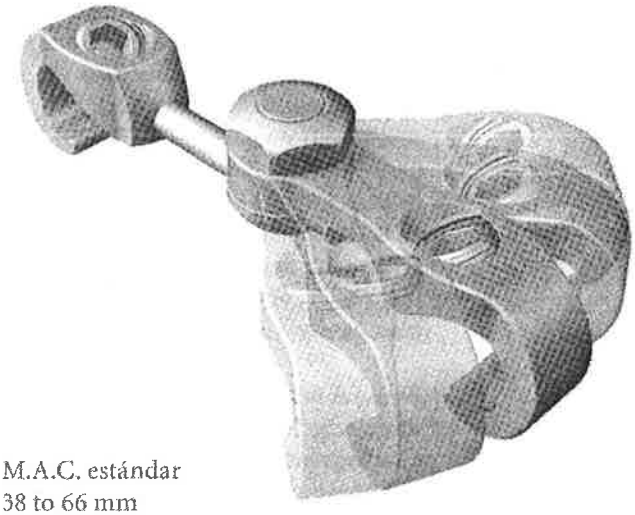
Cuando se utilizan los Tornillos y Ganchos de brazo largo Xia, los brazos se separan una vez que finaliza la reducción. La línea de corte permite separar los brazos fácilmente y con prolijidad. Para separar el primer brazo se utiliza el fórceps para la rotación de la barra sujetando y doblando el brazo con un movimiento hacia atrás y hacia delante.

El segundo brazo se separa de la misma forma que el primero.

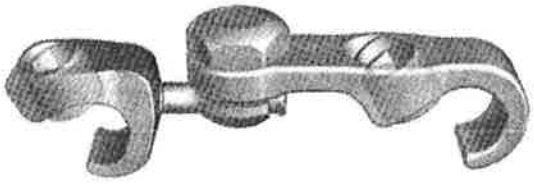


1) Gancho de brazo largo
2) Tornillo de brazo largo

I. Conector multiaxial (M.A.C.)

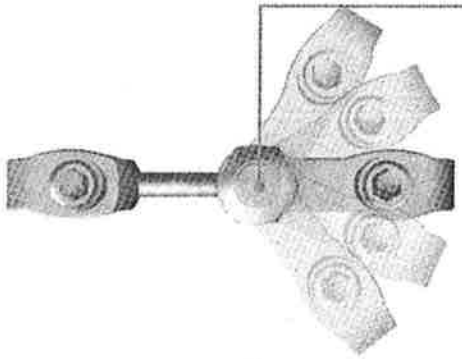


M.A.C. estándar
38 to 66 mm



Pequeño M.A.C. multiaxial
29 to 39 mm

M.A.C. monobloque



Colocación del M.A.C. (Conector multiaxial)

Los dispositivos de unión transversos se utilizan para ayudar a aumentar la estabilidad del montaje.
Generalmente, un M.A.C. es adecuado para la mayoría de los montajes degenerativos. Es posible que los montajes para tumores y traumatismos requieran mayor estabilidad. Esto puede lograrse utilizando una Unión transversa en las partes superior e inferior del montaje.
En la escoliosis, se aconseja utilizar un dispositivo en ambos extremos con un conector medio adicional si el montaje excede los 20 cm de longitud o si requiere mayor estabilidad.

El M.A.C. permite:

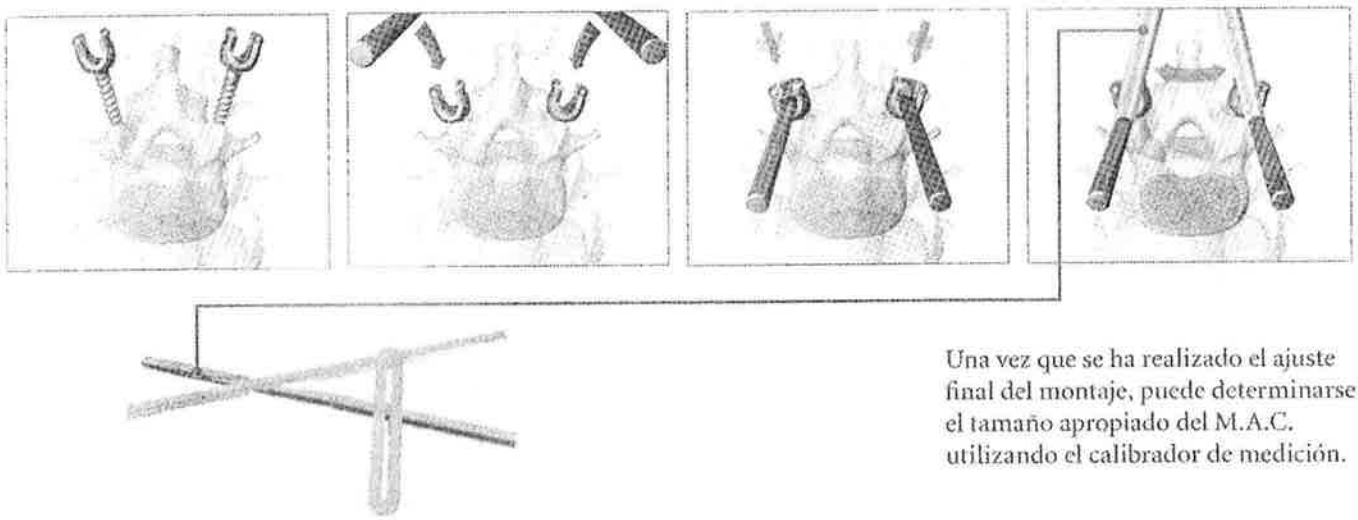
- Más de 180°
- Rango telescópico de 29--99 mm
- Rotación sagital de 360°

Para permitir una colocación suave y rápida del M.A.C. sobre las barras, asegúrese de que el perno central esté flojo para lograr un rango de movimiento total y que los tornillos de ajuste estén hacia afuera.

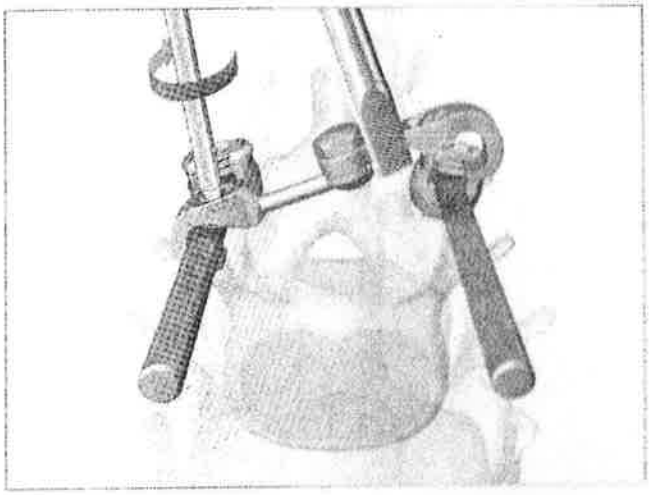
¡IMPORTANTE!
No utilice ningún otro instrumental distinto del instrumental especial para el M.A.C.

I. Conector multiaxial (M.A.C.)

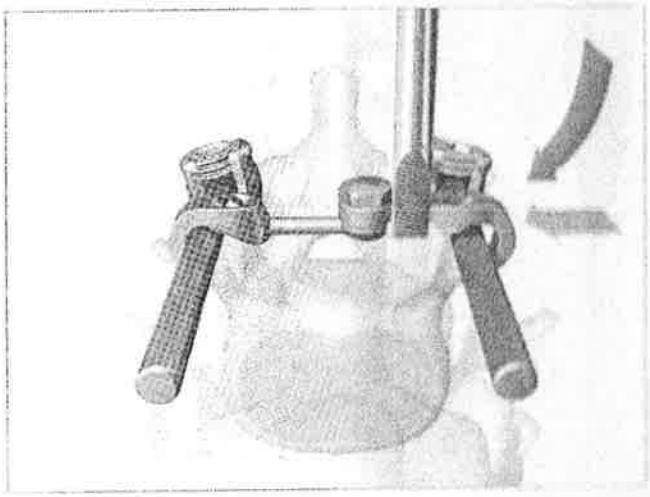
M.A.C. estándar



Una vez que se ha realizado el ajuste final del montaje, puede determinarse el tamaño apropiado del M.A.C. utilizando el calibrador de medición.



Con el Fórceps para el M.A.C. fijo en el gancho más largo con forma de J, coloque el conector de la longitud apropiada en la barra insertando el gancho más corto con forma de J.
Con el destornillador de punta redondeada o estándar, proceda a ajustar suavemente el tornillo de ajuste en la barra.

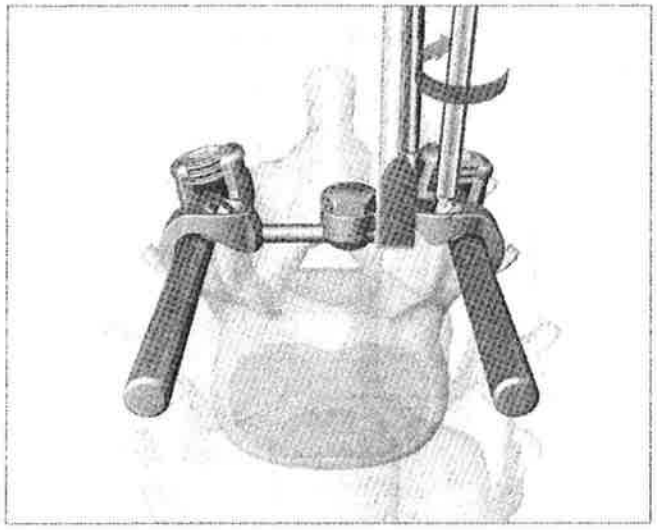


Continúe con la colocación del segundo gancho con forma de J y ajústelo completamente. Regrese al primer tornillo de ajuste para lograr una mayor sujeción.

Verifique que el M.A.C. esté correctamente conectado a las barras (presione firmemente el gancho con forma de J si es necesario).

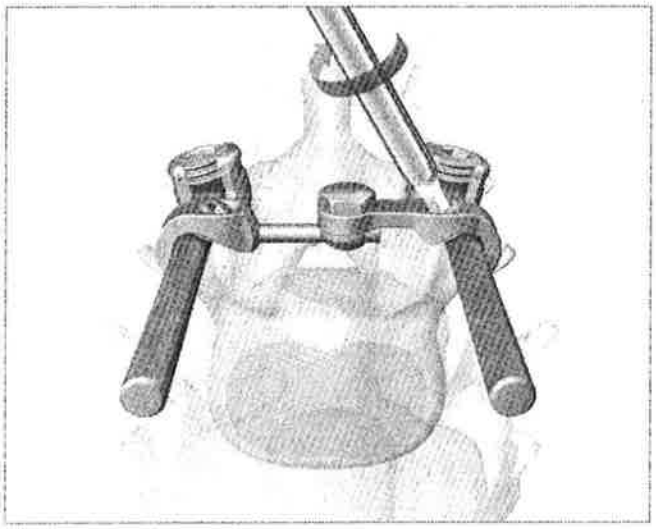
Nota: **Cuando se utiliza el M.A.C. monobloque las barras deben disponerse** en paralelo.

I. Conector multiaxial (M.A.C.)

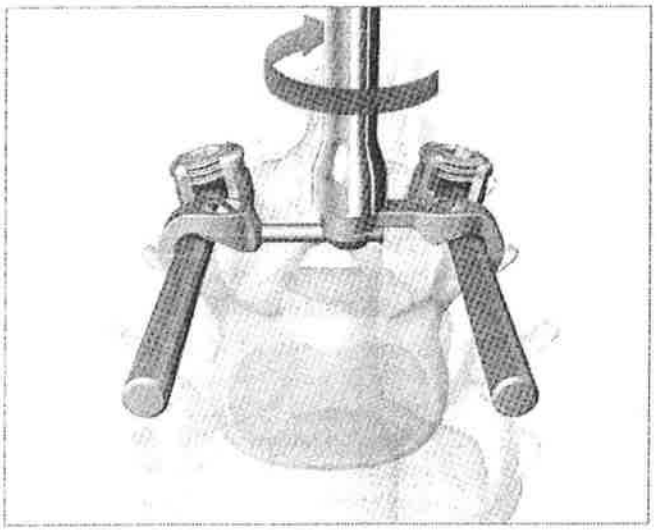


M.A.C. estándar

Nota: El Destornillador de punta redondeada permite una angulación de 35º alrededor de un eje de 360º del tornillo de ajuste.



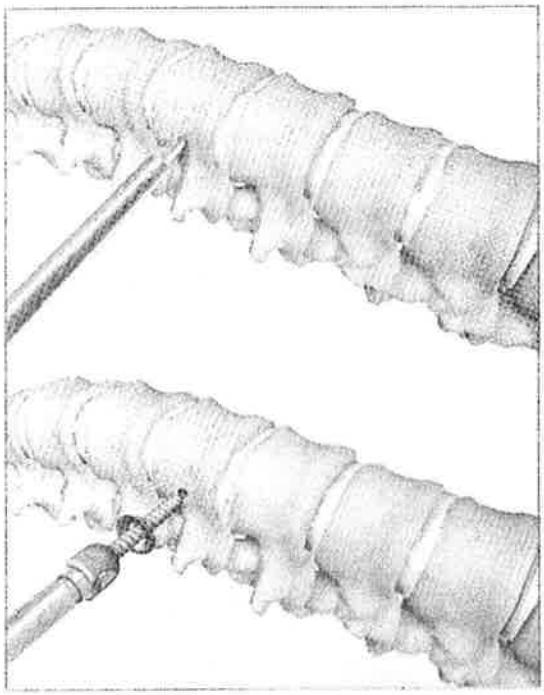
El Destornillador estándar de 3,5 mm debe utilizarse para el ajuste final de los tornillos de ajuste a fin de optimizar la superficie de contacto y evitar dañar el hexágono de los tornillos y la punta del Destornillador de punta redondeada.

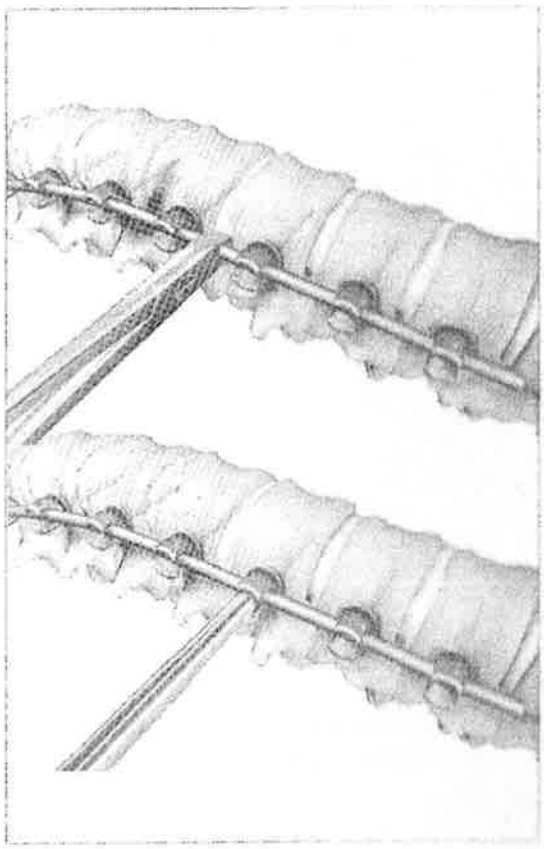


El perno central finalmente se ajusta por completo con el Destornillador hexagonal de 8 mm.

Revise los tornillos colocados afuera para garantizar un ajuste apropiado.

J. Abordaje anterior



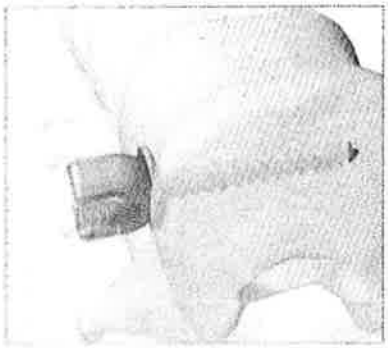


Colocación de los tornillos

Generalmente, se trata al paciente mediante un método transcostal en la columna torácica o mediante un abordaje retroperitoneal en la zona lumbar. Puede utilizarse una incisión combinada para tener acceso a los dos métodos.

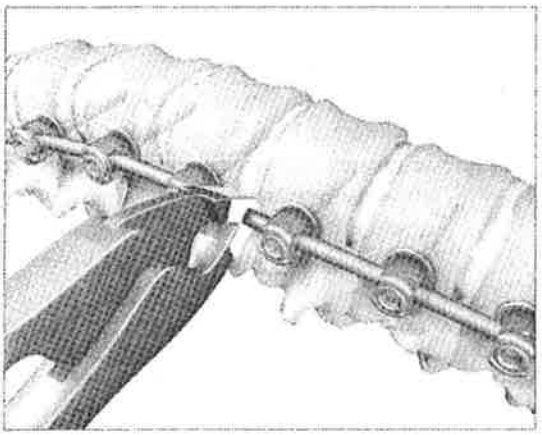
Se coloca al paciente en la posición decúbito lateral con el lado convexo hacia arriba. Se selecciona la vértebra más alta en la que se desea trabajar, lo que por lo general define la costilla que se extirpará (por ejemplo, la 6ª costilla para tener acceso a la 6ª vértebra torácica). La costilla puede extirparse para un injerto óseo.

Se completa la exposición de los cuerpos vertebrales, permitiendo asi disectomías y la liberación del ligamento longitudinal anterior y del tejido blando cóncavo. Probablemente, la extirpación de las placas terminales de las vértebras en esta etapa podría provocar una mayor pérdida de sangre y debería demorarse hasta que finalice la colocación de los tornillos.
Una vez que se define el punto de ingreso y la dirección de los tornillos (colocados en dirección opuesta al canal espinal), puede perforarse la corteza con el Punzón Xia®.



La longitud de los tornillos se selecciona según los resultados obtenidos en Tomografías computarizadas (CT) o el uso de un indicador de profundidad estándar. La cabeza del tornillo debe colocarse a fin de que entre en contacto con la primera corteza o puede agregarse una arandela para lograr una mayor superficie de contacto. Los tornillos se colocan en las arandelas. La sujeción de los tornillos debe ser bicortical para obtener una fijación óptima.

J. Abordaje anterior

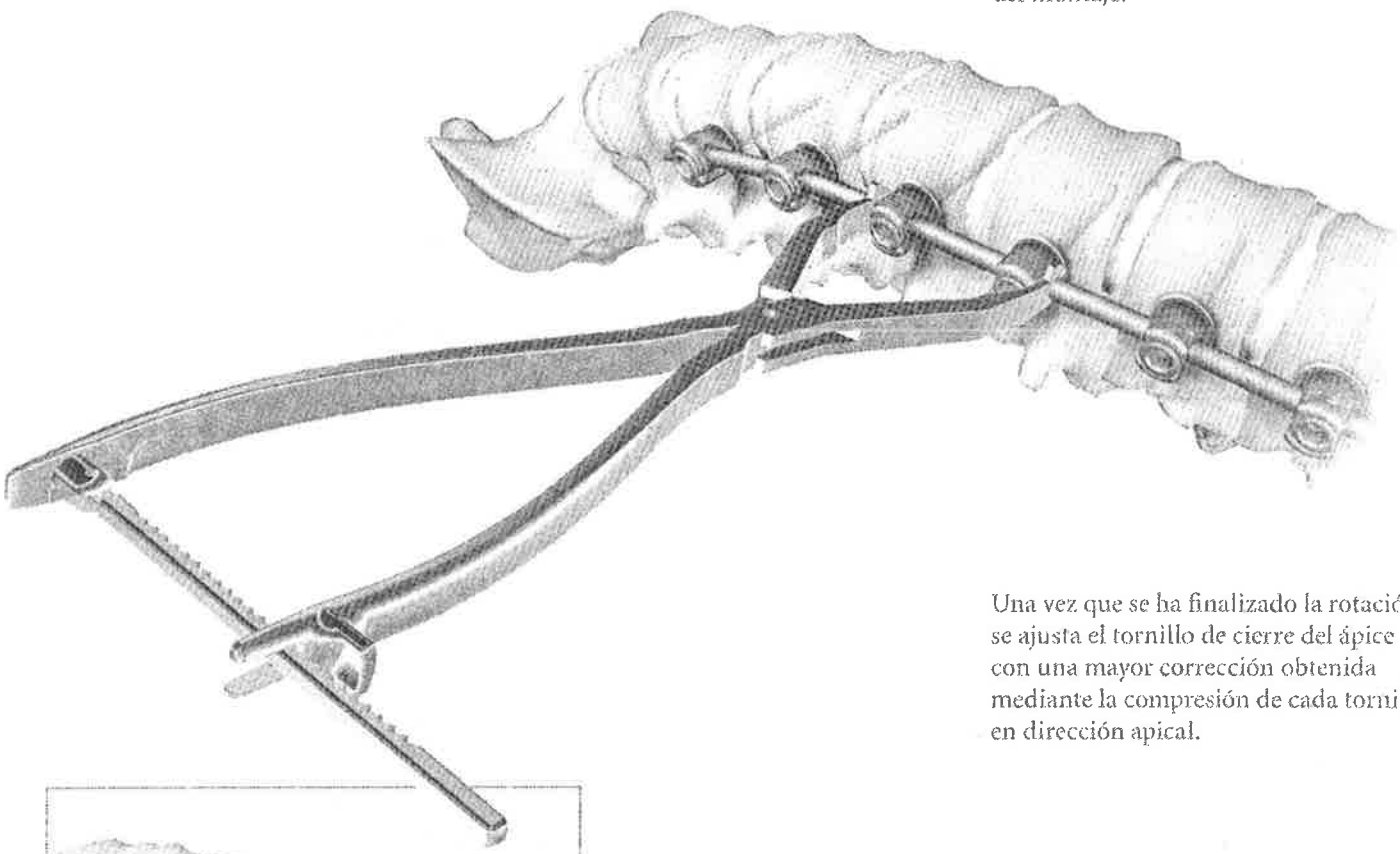


Corrección de la deformidad

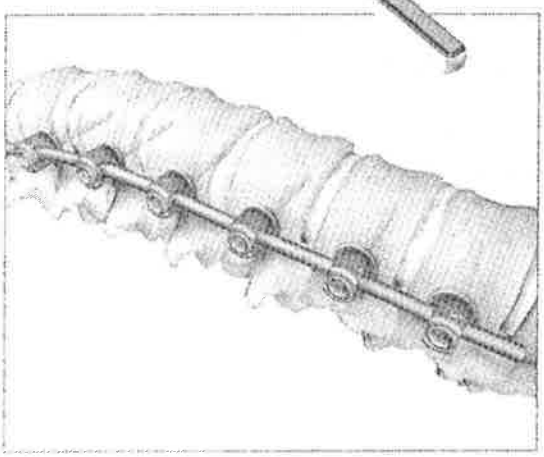
La barra se corta en la longitud apropiada y se curva para que pueda adaptarse a los contornos de la columna.

Se retiran las placas terminales y se realiza un injerto óseo especialmente en la concavidad de la deformidad.
La barra se coloca en la cabeza de los implantes.

Los Tornillos de cierre se introducen parcialmente a fin de permitir la rotación del montaje.



Una vez que se ha finalizado la rotación, se ajusta el tornillo de cierre del ápice con una mayor corrección obtenida mediante la compresión de cada tornillo en dirección apical.



Realice el ajuste final de acuerdo con la secuencia de ajuste estándar (Página 20).

Indicaciones

Indicaciones fuera de EE.UU.

Los Sistemas de fijación para columna STRYKER se indican para una corrección temporal o permanente o para la estabilización de la columna vertebral desde la vértebra torácica al sacro y con el fin de contribuir a la consolidación o fusión ósea. Los SISTEMAS XIA®, OPUS™ y DIAPASON™-RPS™ están diseñados para procedimientos de fijación posterior. XIA® también está diseñado para procedimientos de fijación anterior. Se indican para enfermedades degenerativas de los discos de la columna torácica y lumbar, que se definen como dolor de espalda de origen discogénico con degeneración de disco confirmado por historia clínica y estudios radiográficos, espondilolistesis, fractura, estenosis espinal, deformidades de la columna como escoliosis, cifosis, lordosis, tumor, seudo artrosis o revisión de intentos de fusión fallidos.

Contraindicaciones

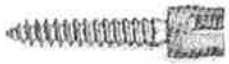
Contraindicaciones

Las contraindicaciones pueden ser relativas o absolutas. La elección de un dispositivo particular debe analizarse minuciosamente teniendo en cuenta la evaluación general del paciente. Las circunstancias descritas a continuación pueden disminuir las posibilidades de un resultado exitoso:

- La presencia de cualquier anormalidad que afecte el proceso normal de la remodelación ósea como osteoporosis severa que compromete a la columna, absorción ósea, osteopenia, tumores primarios o metastáticos que comprometen a la columna, infección activa del sitio y determinados trastornos metabólicos que afectan la osteogénesis, entre otros.
- Calidad o cantidad de hueso insuficiente que inhibiría la fijación de un dispositivo rígido.
- Antecedentes de infección.
- Inflamación local excesiva.
- Heridas abiertas.
- Cualquier déficit neuromuscular que coloque una carga inusualmente pesada sobre el dispositivo durante el período de curación.
- Obesidad. Un paciente obeso o con sobrepeso puede producir cargas en el sistema para columna que pueden provocar la falla de la fijación del dispositivo o del propio dispositivo.
- Pacientes con una cobertura de tejido inapropiada del sitio de la operación.
- Embarazo.
- Enfermedades seniles, trastornos mentales o abuso de sustancias. Estas afecciones, entre otras, pueden hacer que el paciente ignore ciertas limitaciones y precauciones necesarias para el uso del implante, provocando fallas u otras complicaciones.
- Sensibilidad a cuerpos extraños. En los casos en los que se presume la sensibilidad al material, deben realizarse pruebas apropiadas con anterioridad a la selección o al implante del mismo.
- Otras afecciones médicas o quirúrgicas que excluirían el posible beneficio de la cirugía de implante de columna, como la presencia de tumores, anormalidades congénitas, aumento del índice de sedimentación que no tiene su explicación en otras enfermedades, aumentos del recuento de glóbulos blancos o desviación marcada hacia la izquierda en el recuento diferencial de glóbulos blancos.

Estas contraindicaciones pueden ser relativas o absolutas y deben tenerse en cuenta por el médico en el momento de tomar una decisión. La lista detallada arriba no es exhaustiva.

Implantes Xia®

	REF Titanio	REF Acero inoxidable	Descripción		
	03756230	48220000	Mecanismo monoaxial		
	03820425-0445	48220425-0445	Tornillo monoaxial	Ø 4,5 mm	25 mm–45 mm
	03820525-0555	48220525-0555	Tornillo monoaxial	Ø 5,5 mm	25 mm–55 mm
	03820630 - 0600	48220630 - 0600	Tornillo monoaxial	Ø 6,5 mm	30 mm–100 mm
	03820730 - 0700	48220730 - 0700	Tornillo monoaxial	Ø 7,5 mm	30 mm–100 mm
	03820830 - 0800	48220830 - 0800	Tornillo monoaxial	Ø 8,5 mm	30 mm–100 mm
	03820960 - 0900	48220960-0900	Tornillo monoaxial	Ø 9,5 mm	60 mm–100 mm
	03821425 - 1445	48221425-1445	Tornillo poliaxial	Ø 4,5 mm	25 mm–45 mm
	03821525 - 1555	48221525 - 1555	Tornillo poliaxial	Ø 5,5 mm	25 mm–55 mm
	03821630 - 1600	48221630 - 1600	Tornillo poliaxial	Ø 6,5 mm	30 mm–100 mm
	03821730 - 1700	48221730 - 1700	Tornillo poliaxial	Ø 7,5 mm	30 mm–100 mm
	03801830 - 1800	No corresponde	Tornillo poliaxial	Ø 8,5 mm	30 mm–100 mm
	03801960 - 1900	No corresponde	Tornillo poliaxial	Ø 9,5 mm	60 mm–100 mm

	REF Titanio	REF Acero inoxidable	Descripción		
	671040 - 671300	No corresponde	Barras de aleación de titanio	Ø 6,0 mm	40 mm–300 mm
	03802040 - 2480	No corresponde	CP Barras de titanio	Ø 6,0 mm	40 mm–480 mm
	No corresponde	48222000	Barra estándar	Ø 5,5 mm	480 mm
	No corresponde	48222001	Barra rígida	Ø 5,5 mm	480 mm
	48218030 - 8090		Barra rad	Ø 6,0 mm	30 mm–90 mm
	48219050 - 9080		Barra rad máxima	Ø 6,0 mm	50 mm–80 mm
	03805002	48220102	Abrazadera axial de barra a barra		
	03805001	48220103	Abrazadera de barra a barra paralela		
	03820101	48220101	Conector de compensación		
	03820100	48220100	Arandela		
	03820104	48220104	Grapa		
	03805000	No corresponde	Bloque del sacro		
	03805025 - 5035	No corresponde	Bloque del sacro Tornillo para hueso	Ø 6,5 mm	25 mm–35 mm

Implantes Xia®

	REF Titanio	REF Acero inoxidable	Descripción
	03820200	48220200	Gancho laminar pequeño, hoja estándar
	03820201	48220201	Gancho laminar pequeño, hoja estrecha
	03820202	48220202	Gancho laminar grande, hoja estándar
	03820203	48220203	Gancho laminar grande, hoja estrecha
	03820204	48220204	Gancho laminar con cuerpo extendido
	03820206	48220206	Gancho laminar de compensación, derecho
	03820207	48220207	Gancho laminar de compensación, izquierdo
	03820208	48220208	Gancho laminar hoja angulada
	03820210	48220210	Gancho laminar torácico, hoja estándar
	03820211	48220211	Gancho laminar torácico, hoja estrecha
	03820212	48220212	Gancho laminar torácico, pequeño de compensación, derecho
	03820213	48220213	Gancho laminar torácico, pequeño de compensación, izquierdo
	03820214	48220214	Gancho laminar torácico, grande de compensación, derecho
	03820215	48220215	Gancho laminar torácico, grande de compensación, izquierdo
	03820220	48220220	Gancho pedicular, pequeño
	03820221	48220221	Gancho pedicular, grande
	03820230	48220230	Gancho de proceso transverso, derecho
	03820231	48220231	Gancho de proceso transverso, izquierdo
	03820240	48220240	Gancho laminar RBH, hoja estrecha
	03820241	48220241	Gancho laminar RBH, hoja estándar
	03820242	48220242	Gancho laminar RBH, hoja angulada
	03820243	48220243	Gancho laminar torácico RBH, hoja estrecha
	03820244	48220244	Gancho pedicular RBH

Implantes de reducción Xia®

	REF Titanio	REF Acero inoxidable	Descripción		
	Implantes de reducción Xia®				
	03828425-8445	48228425-8445	Brazo largo Tornillo monoaxial	Ø 4,5 mm	25 mm – 45 mm
	03828530-8555	48228530-8555	Brazo largo Tornillo monoaxial	Ø 5,5 mm	30 mm – 55 mm
	03828630-8660	48228630-8660	Brazo largo Tornillo monoaxial	Ø 6,5 mm	30 mm - 60 mm
	03828730-8760	48228730-8760	Brazo largo Tornillo monoaxial	Ø 7,5 mm	30 mm - 60 mm
	03829425-9445	48229425-9445	Brazo largo Tornillo poliaxial	Ø 4,5 mm	25 mm – 45 mm
	03829530-9555	48229530-9555	Brazo largo Tornillo poliaxial	Ø 5,5 mm	30 mm -55 mm
	03829630-9660	48229630-9660	Brazo largo Tornillo poliaxial	Ø 6,5 mm	30 mm - 60 mm
	03829730-9760	48229730-9760	Brazo largo Tornillo poliaxial	Ø 7,5 mm	30 mm - 60 mm
	03827203	48227203	Gancho laminar de brazo largo, hoja grande, estrecha		
	03827201	48227201	Gancho laminar de brazo largo, hoja pequeña, estrecha		
	03827202	48227202	Gancho laminar de brazo largo, hoja grande, estándar		
	03827211	48227211	Gancho laminar torácico de brazo largo, hoja estándar		
	03827220	48227220	Gancho pedicular de brazo largo, pequeño		

Aplicación universal Xia
Instrumentos Xia®

	REFERENCIA	Descripción
	Instrumentos estándar	
	48047029	Impactador para ganchos Xia
	03807019	Impulsador de barra Xia
	03710620	Plantilla para barra Xia
	03807003	Varilla sensible Xia (serie de 4)
	03807024	Sonda de aguja corta Xia
	03807021	Preparador para ganchos de la lámina Xia
	48047011L/R	Instrumento para curvar Xia
	03807010	Curvadora francesa Xia
	03807004	Trepanador Xia, 4,5 / 5,5 mm
	03807005	Trepanador Xia, 6,5 / 7,5 mm

Instrumentos Xia®

	REFERENCIA	Descripción
	Instrumentos estándar	
	03807002	Localizador de sonda Xia
	03807001	Punzón Xia
	03807008	Tensor universal Xia, 5 mm
	48047009	Insertor Xia
	48047018	Horquilla de la barra Xia
	48047016	Persuasor Xia
	03807028	Llave de torsión Xia
	03807026	Llave anti-torsión Xia
	48047800	Tenazas de corte Xia
	48040230	Cable tipo K

Aplicación universal Xia
Instrumentos Xia®

	REFERENCIA	Descripción
	Instrumentos estándar	
	48026100	Compresor
	**48026000**	Distractor
	**48040030**	Anillo en C
	**48040110**	Preparador para ganchos de la lámina - 4,5 mm
	**48041310**	Nuevo destornillador Xia, poliaxial
	48041311	Nuevo poliaxial Xia, eje
	**48041320**	Nuevo destornillador Xia, monoaxial
	48041321	Nuevo monoaxial Xia, eje
	**03807030**	Mango del destornillador Xia
	**48040090**	Clip de orientación
	**48040100**	Fórceps para rotación de barra

Instrumentos Xia®

	REFERENCIA	Descripción
	Instrumentos estándar	
	48047025	Preparador para ganchos pediculares
	48040040	Fórceps para ganchos laterales
	48040140	Fórceps para colocación de barra
	48041020	Fórceps para ganchos
	03807031	*Atornillador poliaxial
	03807006	*Destornillador poliaxial
	48040005	Bandeja para instrumental común
	48040001	Bandeja para tornillos Xia (SS)
	48040007	Bandeja para ganchos Xia (SS)
	48040006	Bandeja para ganchos Xia (Ti)

*Para conectores, revisión y tornillos poliaxiales de 8.5 mm

stryker

Reemplazo de articulaciones

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Craneomaxilofacial

Columna vertebral

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Productos quirúrgicos

Neurología y ORL

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Navegación

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Equipo de manipulación del paciente

Equipo EMX

Stryker Latin America
3000 SW 148th Avenue
Suite 300
Miramar, Florida 33027
Teléfono: +954 538 8200
Fax: +954 538 8215
Sitio Web: www.stryker.com/latinamerica

Xia es una marca registrada de Stryker Spine.

La información presentada en este folleto tiene como objetivo mostrar un producto de Stryker. Siempre consulte el material impreso incluido dentro del paquete, la etiqueta del producto y/o las instrucciones de uso antes de utilizar cualquier producto de Stryker. Es posible que los productos no estén disponibles en todos los mercados. La disponibilidad del producto está sujeta a las reglamentaciones o prácticas médicas que rigen en cada mercado en particular. Comuníquese con su representante de Stryker si desea formúlar preguntas acerca de la disponibilidad de los productos Stryker en su zona.

Los productos con la designación ™ son marcas comerciales de Stryker.
Los productos con la designación ® son marcas comerciales registradas de Stryker.

LXSDOT-ESP

Número de literatura: LXSDOT-ESP
MTX/GS 10/06

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stryker

Osteosynthesis

T2
Humeral Nailing System

Operative Technique

T2 Humeral Nailing System

Contributing Surgeons

Rupert Beickert, M.D.
Senior Trauma Surgeon
Murnau Trauma Center
Murnau
Germany

Rosemary Buckle, M.D.
Orthopaedic Associates, L.L.P.
Clinical Instructor
University of Texas Medical School
Houston, Texas
USA

Prof. Dr. med. Volker Bühren
Chief of Surgical Services
Medical Director of Murnau Trauma Center
Murnau
Germany

Michael D. Mason, D.O.
Assistant Professor of Orthopaedic Surgery
Tufts University School of Medicine
New England Baptist Bone & Joint Institute
Boston, Massachusetts
USA

This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is required prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions

See package insert (L22000007) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Warning:

All bone screws referenced in this document here are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Contents

Introduction

Over the past several decades **antegrade humeral nailing** has become the treatment of choice for most humeral shaft fractures. **Retrograde humeral nailing** has expanded the use of intramedullary nails.

Studies have shown the following benefits to be associated with Humeral Nailing:
Brief operative time (1)
Minimal morbidity (1)
Early return to function of the extremity (2)
In 90% of the cases, no external support is needed (1, 2)
Closed technique (4)
Low infection rate (2, 5, 6)
Very good pain relief in stabilization of pathological fractures (2, 4)

Compared to Plate and Screw Osteosynthesis:
Minimal damage to muscle, connective tissue and vasculature (1, 3, 7)
Reduced periosteal stripping and concomitant soft tissue damage(1)
Fewer radial nerve palsies (3, 4)
Designed for load sharing instead of load bearing (2)
Cosmetically smaller incision

The T2 Humeral Nailing System is one of the first humeral nailing systems to offer an option for either an antegrade or a retrograde approach to repair fractures of the humerus.

One Implant, Two Approaches

Stryker Osteosynthesis has created a locking nail system, bring-ing together all the capabilities and benefits of separate antegrade and retrograde nailing systems to create **a single, integrated surgical resource** for fixation of long-bone fractures.
Furthermore, the development of the T2 Humeral Nailing System offers the competitive advantages of:

- **Dual nailing approach: Antegrade and Retrograde**
- **Accommodating reamed or unreamed procedures**
- **Static, controlled dynamic and apposition/compression locking options**
- **Advanced Locking Mode for increased rotational stability.**

Through the development of a common, streamlined and intuitive surgical approach, both in principle and in detail, the T2 Humeral Nailing System offers significantly increased speed and functionality for the treatment of fractures as well as simplifying the training requirements for all personnel involved.

Implant Features

The T2 Humeral Nailing System is the realization of superior biomechanical intramedullary stabilization.

The system offers the option of different locking modes:
- **Static, transverse/oblique**
- **Dynamic**
- **Apposition/compression**
- **Advanced locking**

In some indications, **a controlled apposition/compression of bone fragments can be applied by introducing a compression screw from the top of nail.** To further increase rotational stability, the nail can be locked after utilizing the apposition/compression feature.

The beneficial effect of apposition/compression in treating long-bone fractures in cases involving transverse and short oblique fractures that are axially stable is well documented (15, 16, 19).

The compression screw is pushed against the proximal Partially Threaded Locking Screw (Shaft Screw) that has been placed in the oblong hole, **drawing either the distal or the proximal segment towards the fracture site.** In stable fractures, this has the biomechanical advantage of **creating active circumferential compression** to the fracture site, **transferring axial load to the bone,** and reducing the function of the nail as a load bearing device (17).

This ability to transfer load back to the bone can reduce the incidence of implant failure secondary to fatigue. Typical statically locked nails functioning as load bearing devices have reported failure rates in excess of 20% (18).

Common 4mm cortical screws simplify the surgical procedure. Fully **Threaded Locking Screws** are available for regular locking procedures. **Partially Threaded Locking Screws (Shaft Screws)** are designed for application of apposition/compression.

One **common Humeral Compression Screw** to close the fracture site, and End Caps in six sizes are available to provide an improved fit for every indication to allow nail length adaptation after insertion and to prevent bone ingrowth.

All implants of the T2 Humeral Nailing System are cannulated and made of **Type II anodized titanium alloy (Ti6AL4V) for enhanced biomechanical and biomedical performance.**

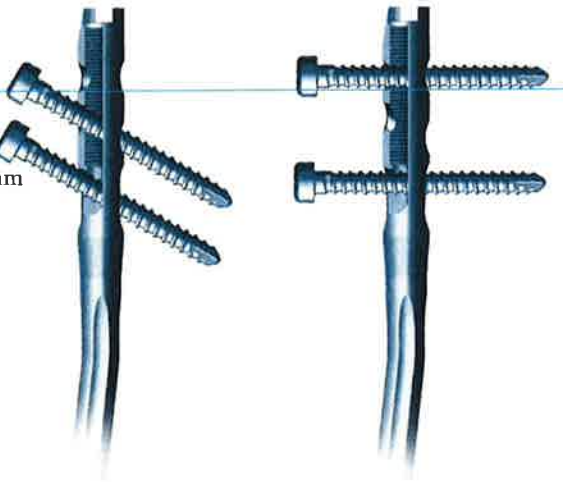
See the detailed chart on the next page for the design specifications and size offerings.

Introduction

Technical Details

Nails

Diameter 7–9mm
Sizes 140–320mm



Humerus Advanced Compression Screw
(Diameter = 6mm)

4.0mm Fully Threaded Locking Screws
L = 20–60mm

4.0mm Partially Threaded Locking Screws
(Shaft Screws)
L = 20–60mm

End Caps

* Compression Range

Total Length of Slot	10mm
Less Screw Diameter (–)	4mm
Maximum Movement of Screw	6mm

Introduction

Instrument Features

The major advantage of the instrument system is a breakthrough in the integration of the instrument platform which can be used not only for the complete T2 Nailing System, but will be the platform for all future Stryker nailing systems, thereby reducing complexity and inventory.

The instrument platform offers advanced precision and usability, and features ergonomically styled targeting devices.

Symbol coding on the instruments indicates the type of procedure, and must not be mixed.

Symbol

■ Square = Long instruments

▲ Triangular = Short instruments

Drills

Drills feature color coded rings:

3.5mm = Orange
For 4.0mm Fully Threaded Locking Screws and for the second cortex when using 4.0mm Partially Threaded Locking Screws (Shaft Screws).

4.0mm = Grey
For the first cortex when using 4.0mm Partially Threaded Locking Screws (Shaft Screws).

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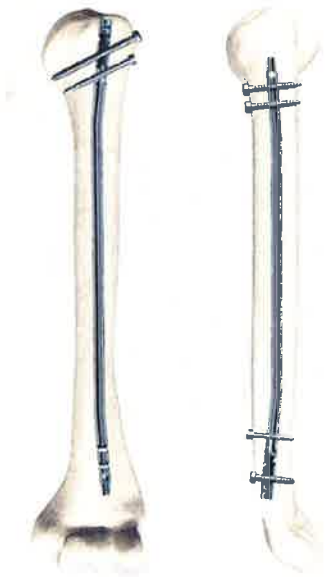
Indications, Precautions and Contraindications

Indications

- The T2 Humeral Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunions of the humerus.
- The nails are inserted using an opened or closed technique and can be static, dynamic and compression locked.
- The subject and predicate devices are indicated for use in the humerus.
- Types of fractures include, but not limited to fractures of the humeral shaft, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

Precautions

The T2 System has not been evaluated for safety and compatibility in the MR environment.
The T2 System has not been tested for heating or migration in the MR environment.



Relative Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Pre-operative Planning

An X-Ray Template (1806-0003) is available for pre-operative planning.

Thorough evaluation of pre-operative radiographs of the affected extremity is critical. Careful radiographic examination can help prevent intra-operative complications.

If X-Rays show a very narrow intramedullary canal in the distal part of the humerus, retrograde humeral nailing is not possible.

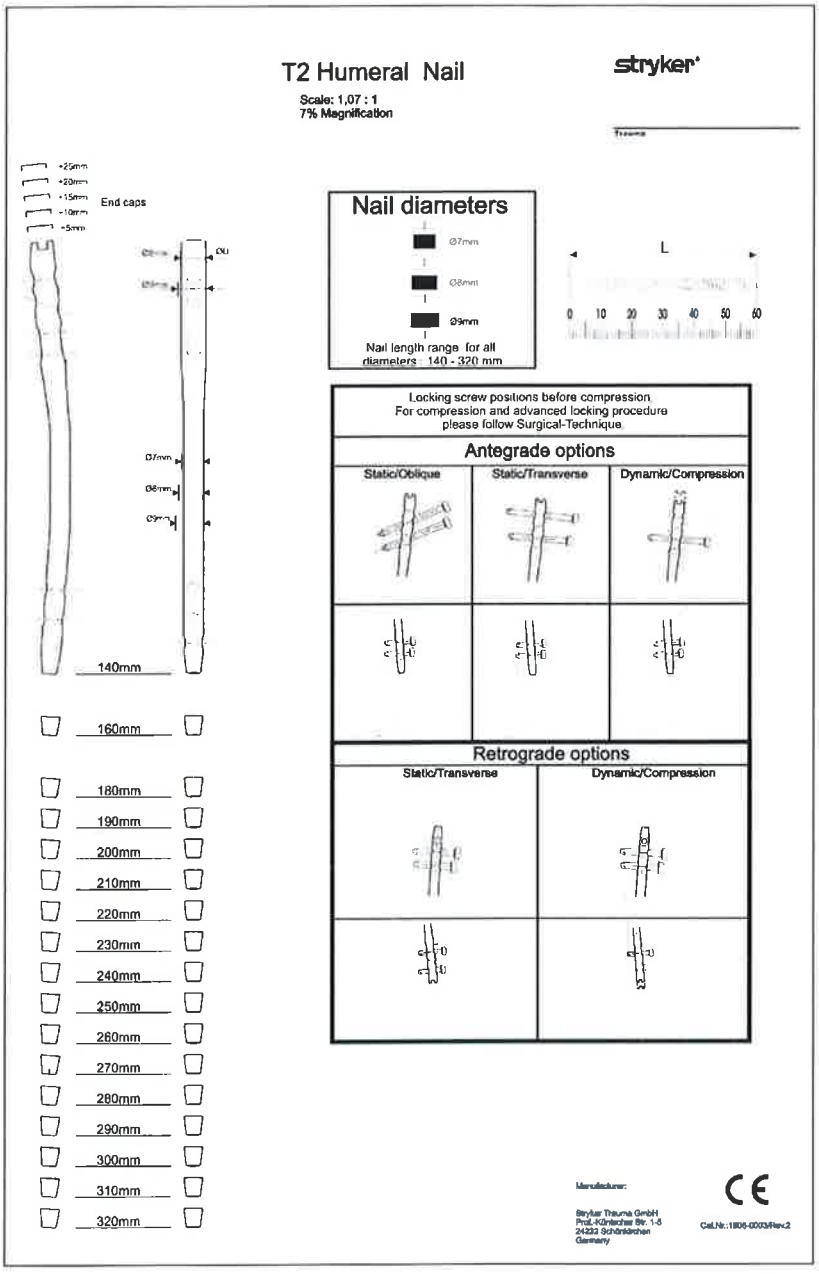
The proper nail length when inserted antegrade should extend from sub-chondral bone proximally, to 1cm above the olecranon fossa distally.

The retrograde nail length is determined by measuring the distance from 1cm above the olecranon fossa to the center of the humeral head.

In either approach, the surgeon should consider the apposition/compression feature of the T2 Humeral Nail, knowing that 6mm of active apposition/compression is possible, prior to determining the final length of the implant.

Note:

Check with local representative regarding availability of nail sizes.



Locking Options

Antegrade

Static Mode transverse

Static Mode oblique

Retrograde

Locking Options

Dynamic Mode

Apposition/Compression Mode

Advanced Locking Mode

Operative Technique – Antegrade Technique

Patient Positioning and Fracture Reduction

The patient is placed in a semireclined "beach chair position" or supine on a radiolucent table. Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the affected extremity (Fig. 1). The image intensifier is placed at the legside of the patient; the surgeon is positioned at the headside.

Fig. 1

Incision

A small incision is made in line with the fibers of the deltoid muscle anterolateral to the acromion. The deltoid is split to expose the subdeltoid bursa. Palpate to identify the anterior and posterior margins of the greater tuberosity and supraspinatus tendon. The supraspinatus tendon is then incised in line with its fibers (Fig. 2).

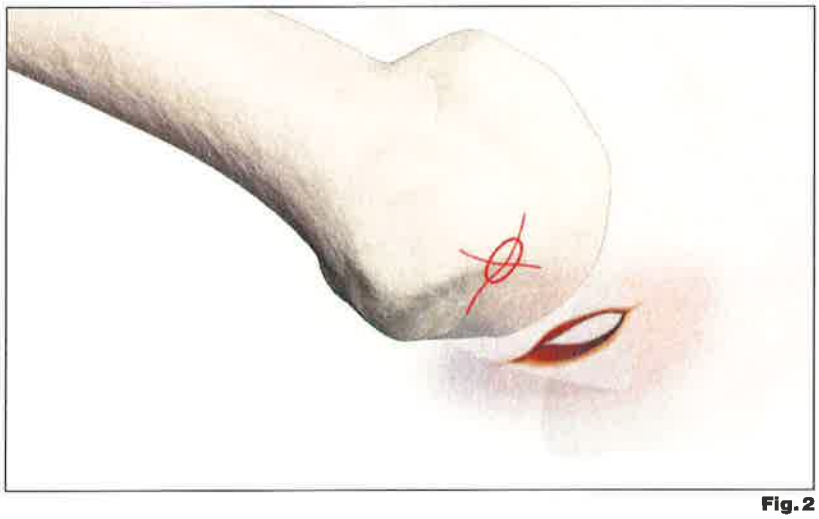


Fig. 2

The real rotation of the proximal fragment is checked (inversion or reversion), considering that the entry point is at the tip of the greater tubercle. If the proximal fragment is inverted, the entry point is more anterior. If the proximal fragment is in external rotation, the entry point is more lateral. It is recommended to localize the entry point under image intensifier control, also palpating the bicipital groove, the portal is about 10mm posterior to the biceps tendon. This will make the entry portal concentric to the medullary canal.

Operative Technique – Antegrade Technique

Entry Point

The entry point is made with the Curved, cannulated Awl (1806-0040) (Fig. 3). The 2.5×800mm Ball Tip Guide Wire (1806-0083S) is then introduced through the awl under image intensification into the meta-physis, central to the long axis of the humerus.

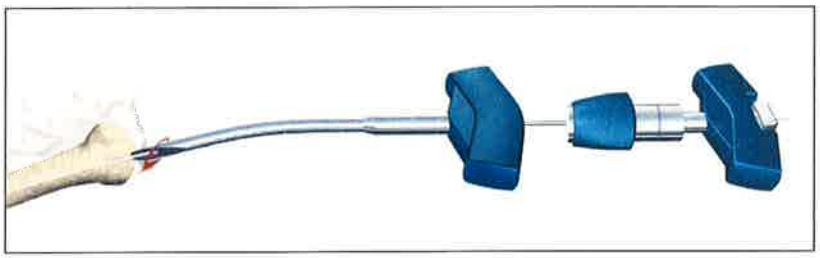


Fig. 3

Alternatively, the optional Crown Drill (1806-2020) may be used over the K-Wire with Washer (1806-0051S) for entry point preparation. The K-Wire will help to guide the Crown Drill centrally (Fig. 3a).

Then, the 3×285mm K-Wire (1806-0050S) is introduced under image intensification into the meta-physis, central to the long axis of the humer-us.

The cannulated Ø10mm Rigid Reamer (1806-2010) may be used over the K-Wire and the proximal metaphysis should be drilled to a depth of at least 6cm.

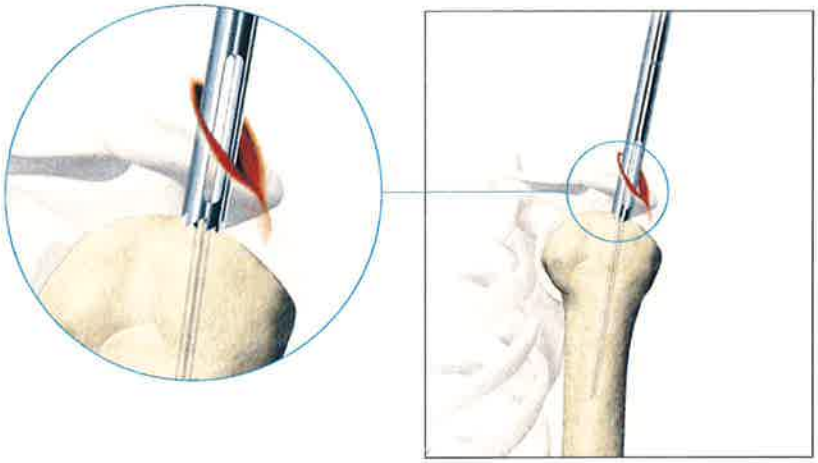


Fig. 3a

Note:

During opening the entry portal with the Awl, dense cortex may block the tip of the Awl. An Awl Plug (1806-0032) can be inserted through the Awl to avoid penetra-tion of bone debris into the can-nulation of the Awl shaft.

Operative Technique – Antegrade Technique

Unreamed Technique

If an unreamed technique is preferred, the nail may be inserted over the 2.2×800mm Smooth Tip Guide Wire (1806-0093S) (Fig. 4).

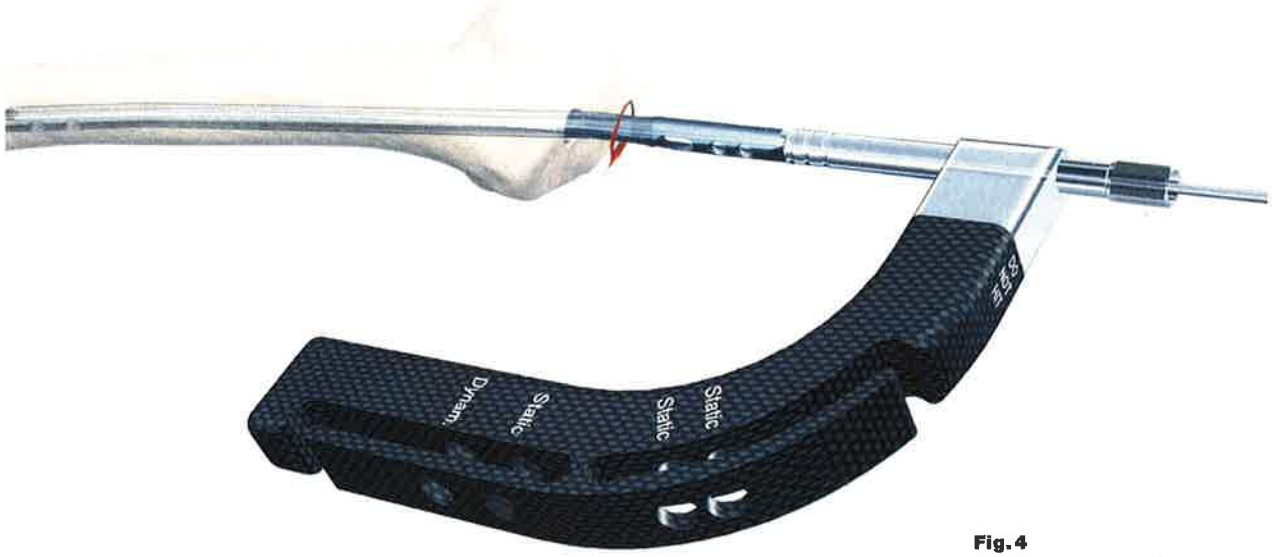


Fig. 4

Reamed Technique

For reamed techniques, the 2.5×800mm Ball Tip Guide Wire (1806-0083S) is inserted across the fracture site.
The Reduction Rod (1806-0363) may be used as a fracture reduction tool to facilitate Guide Wire insertion across the fracture site (Fig. 5).

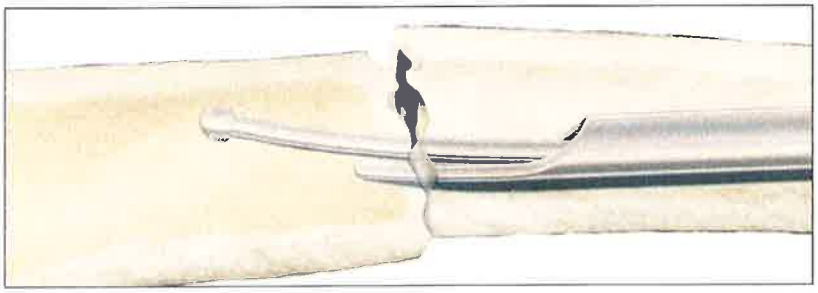


Fig. 5

Reaming is commenced in 0.5mm increments until cortical contact is appreciated. Final reaming should be 1mm–1.5mm larger than the diameter of the nail to be used.

The Guide Wire Pusher can be used to help keep the Guide Wire in position during reamer shaft extraction. The metal cavity at the end of the handle pushed on the end of the power tool facilitates to hold the Guide Wire in place when starting to pull the power tool. When close to the Guide Wire end place the Guide Wire Pusher with its funnel tip to the end of the power tool cannulation. While removing the power tool the Guide Wire Pusher will keep the Guide Wire in place (Fig. 6&7).

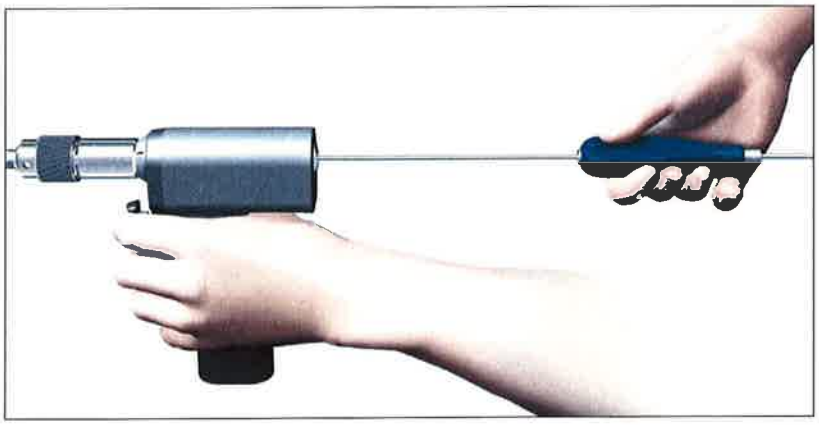


Fig. 6

Operative Technique – Antegrade Technique

Note:

- **8mm Humeral Nails cannot be inserted over the 3 × 1000mm Ball Tip Guide Wire (1806-0085S). The Ball Tip Guide Wire must be exchanged for the 3 × 800mm Smooth Tip Guide Wire (1806-0090S) prior to nail insertion.**
- **Use the Teflon Tube (1806-0073S) for the Guide Wire exchange.**

When reaming is completed, the Teflon Tube (1806-0073S) should be used to exchange the Ball Tip Guide Wire (1806-0083S) with the Smooth Tip Guide Wire (1806-0093S) for nail insertion (Fig. 8 and 9).

An unreamed technique can be considered in cases, where the medullary canal has the appropriate diameter. In these cases, the nail can be introduced over the 2.2×800mm Smooth Tip Guide Wire (1806-0093S).

Note:

- **X-Ray Templates should be used pre-operatively to determine the canal size radiographically.**
- **The driving end of 7mm nails is 8mm.**

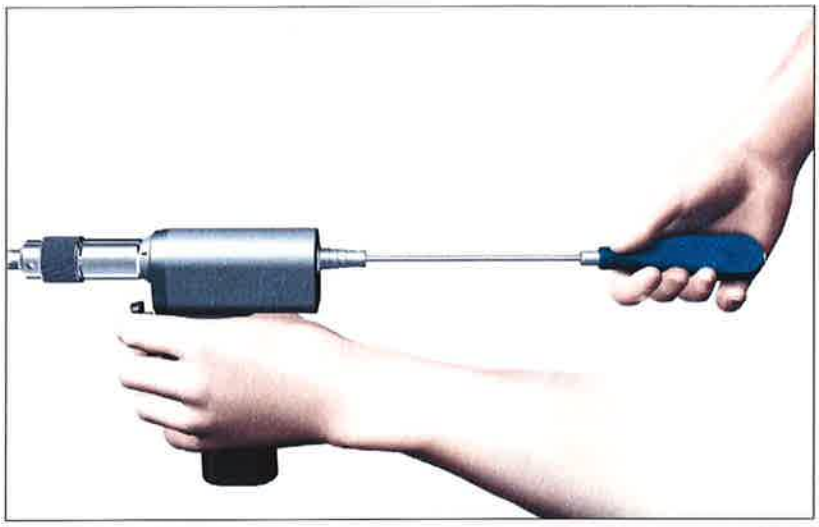


Fig. 7

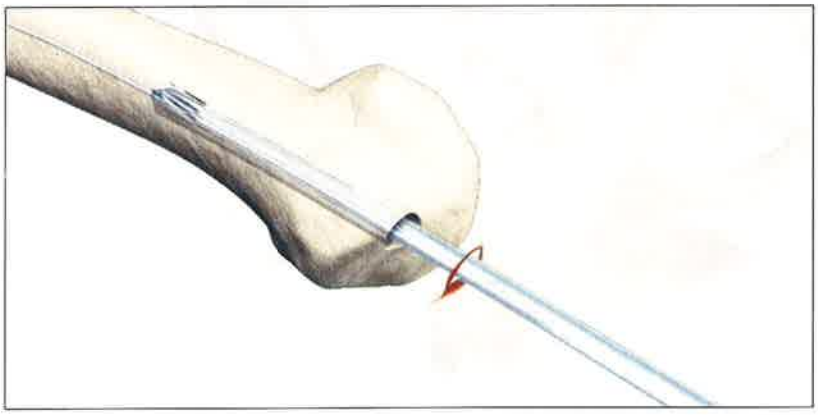


Fig. 8

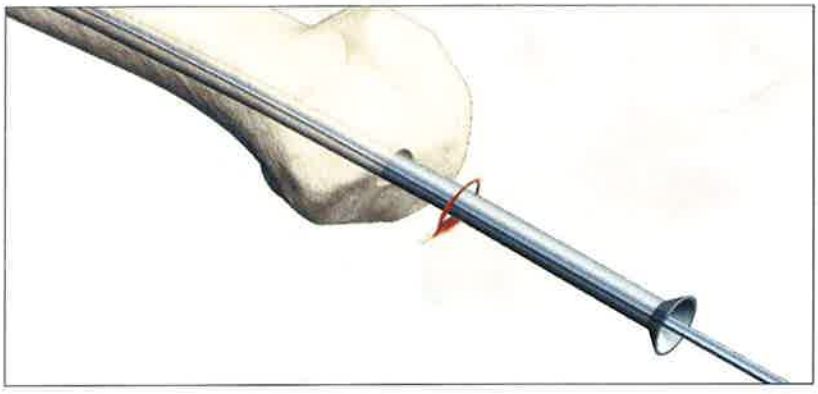


Fig. 9

Operative Technique – Antegrade Technique

Nail Selection

The X-Ray Template should be used pre-operatively to determine the canal size radiographically. This information may be utilized in conjunction with the clinical assessment of canal size as determined by the size of the last reamer used.

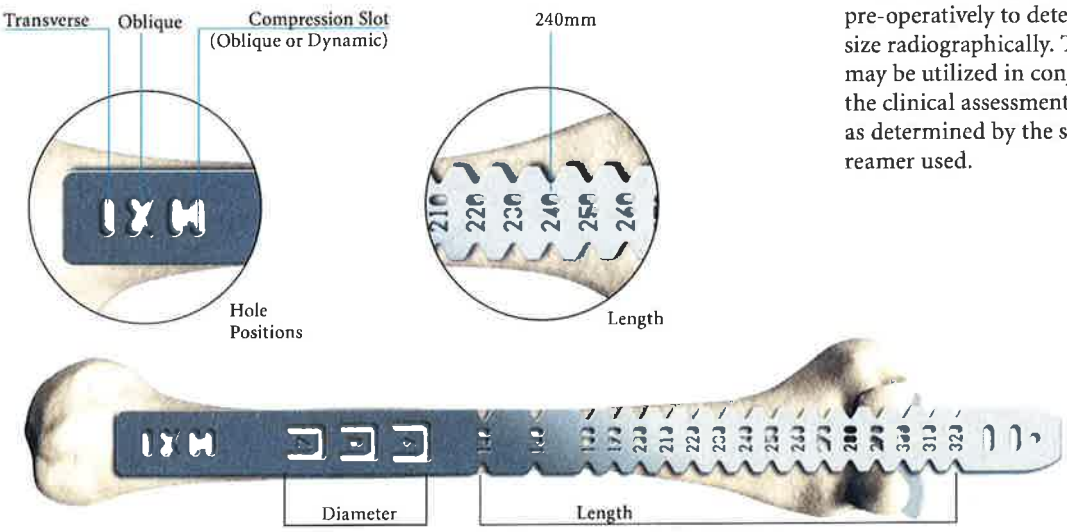


Fig. 10

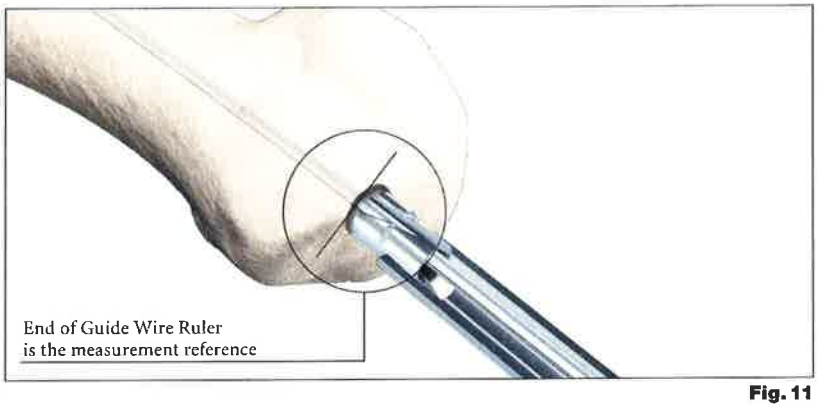


Fig. 11

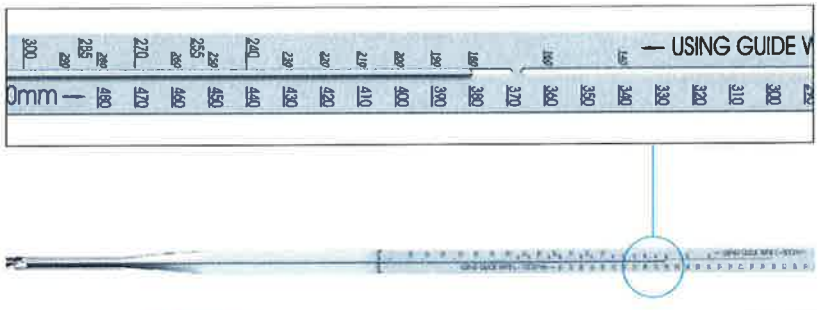


Fig. 12

The Guide Wire Ruler can be easily folded and unfolded.

Diameter

The diameter of the selected nail should be 1mm–1.5mm smaller than the last reamer used.

Length

Nail length may be determined with the X-Ray Ruler (Fig. 10). The Guide Wire Ruler (1806-0022) may be used by placing it on the Guide Wire reading the correct nail length at the end of the Guide Wire on the Guide Wire Ruler (Fig. 11 and 12). Confirm the position of the tip of the Guide Wire prior to measurement.

Note:

If the fracture is suitable for apposition/compression, the implant selected should be 6–10mm shorter than measured to help avoid migration of the nail beyond the insertion site.

Nail Insertion

The selected nail is assembled onto the Target Device (1806-0143) with the Nail Holding Screw (1806-0163). Tighten the Nail Holding Screw securely with the Insertion Wrench (1806-0135) so that it does not loosen during nail insertion (Fig. 13).

Fig.13

Note:

Prior to nail insertion please check correct alignment by inserting a drill bit through the assembled Tissue Protection and Drill Sleeve placed in the required holes of the targeting device.

Upon completion of reaming and Guide Wire exchange, the appropriate size nail is ready for insertion. Advance the nail through the entry point past the fracture site to the appropriate level.

Fig.14

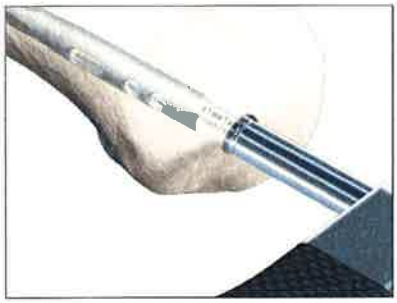


Fig.15

Gentle rotation of the nail may be necessary to start the nail insertion. The nail should be advanced with manual pressure. Aggressive use of the slotted hammer can result in additional fractures. If the nail does not advance easily, a check with image intensification should be made to see if the nail angle is too steep resulting in the nail impinging on the medial cortex.

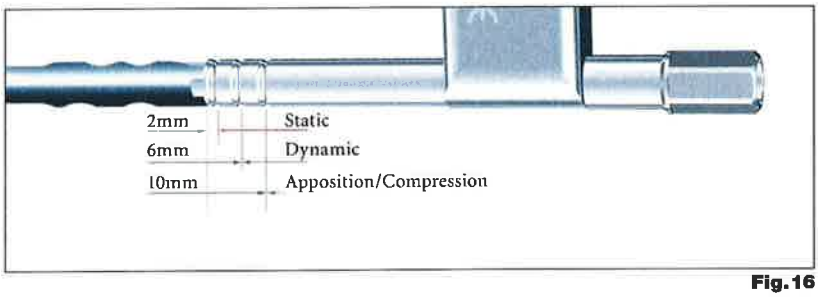


Fig.16

The Slotted Hammer (1806-0170) can be used to insert the nail over the Guide Wire.
DO NOT hit the Target Device.

Note:

A chamfer is located on the working end of the nail to denote the end under X-Ray. Three circumferential grooves are located on the insertion post at 2mm, 6mm, and 10mm from the driving end of the nail (Fig. 14-16). Depth of insertion may be visualized with the aid of fluoroscopy.

Fig.17

The 3×285mm K-Wire may be inserted through the Target Device which identifies the junction of the nail and insertion post (Fig. 17).

Operative Technique – Antegrade Technique

Guided Locking Mode (via Target Device)

Prior to guided locking via the Target Device, the Nail Holding Screw must be firmly tightened using the Insertion Wrench, to ensure that the nail is in correct alignment with the Target Device.

The Target Device is designed to provide four options for guided locking (Fig. 18.1–18.4).

In the Static Oblique Locking Mode, the two static holes closest to the end of the nail may be used for static oblique (30°) locking (Fig. 18.1).
1. Static
2. Static

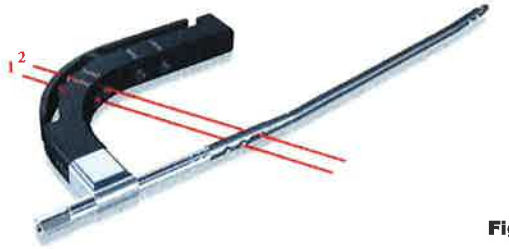


Fig. 18.1

In the Static Transverse Locking Mode, the next static hole and the dynamic hole are used for static transverse locking (Fig. 18.2).
3. Static
4. Dynamic

Fig. 18.2

In the Controlled Dynamic Mode, and/or Controlled Apposition/Compression Mode, the dynamic hole is required (Fig. 18.3).
4. Dynamic

Fig. 18.3

In the Advanced Locking Mode, the dynamic hole is required. After utilizing compression with the Advanced Compression Screw, the static hole is used (Fig. 18.4).
4. Dynamic
3. Static

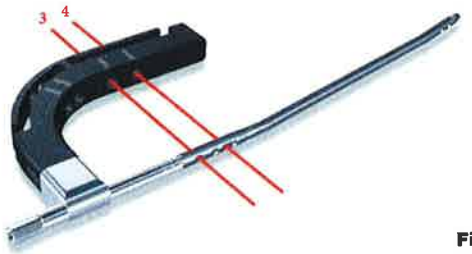


Fig. 18.4

The Short Tissue Protection Sleeve, (1806-0180), together with the Short Drill Sleeve (1806-0210) and the Short Trocar (1806-0310), are inserted into the Target Device by pressing the safety clip (Fig. 19).

The friction lock mechanism is designed to keep the sleeve in place and prevent it from falling out. It is designed to also keep the sleeve from sliding during screw measurement. To release the Tissue Protection Sleeve, the safety clip must be pressed again.

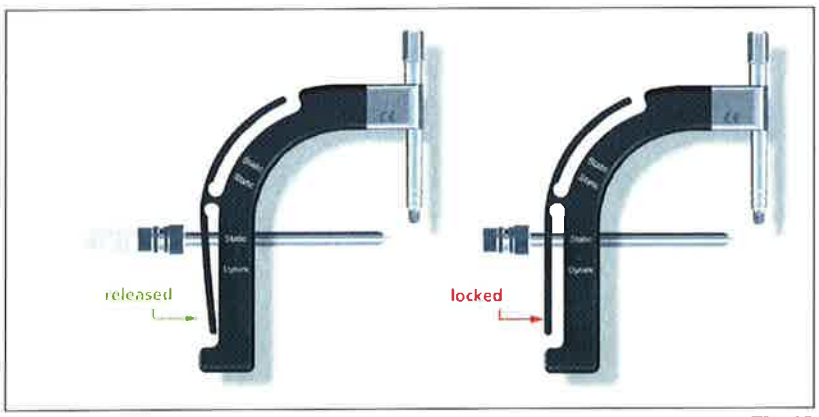


Fig. 19

Static Locking Mode

Static Transverse Locking Mode

In unstable or comminuted fractures, the nail should be used as a standard interlocking nail. Static locking of the distal holes will help maintain the length of the bone and the rotational stability of the fracture.

The Short Tissue Protection Sleeve, together with the Short Drill Sleeve and the Short Trocar, are positioned through the static locking hole on the Target Device. A small skin incision is made, and the assembly is pushed through until it is in contact with the lateral cortex of the humerus (Fig.20).

Fig. 20

Note:

Especially in the proximal humerus, use image intensification to help ensure the Tissue Protection Sleeve is flush with the cortex or you could lose 1–2mm of screw measurement accuracy.

The Trocar is removed while the Tissue Protection Sleeve and the Drill Sleeve remain in position.

For accurate drilling and easy determination of screw length, use the center-tipped, Ø3.5×230mm calibrated Drill (1806-3540S). The centered Drill is forwarded through the Drill Sleeve and pushed onto the cortex.
After the first cortex is drilled to the appropriate level the screw length may be read directly off of the Drill at the end of the Drill Sleeve (Fig. 21).

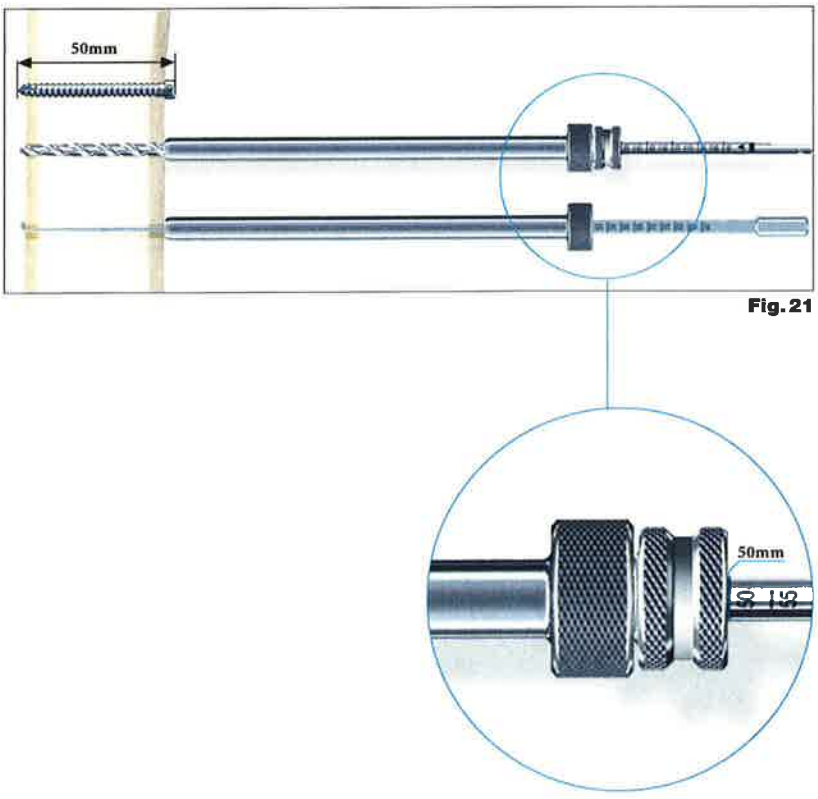


Fig. 21

Caution:

Make sure the Tissue Protection Sleeve/Drill Sleeve Assembly is seated on bone prior to selecting final screw length.

Operative Technique – Antegrade Technique

Warning:

Do not drill through the far cortex as this will penetrate the joint.

Note:

- **The position of the end of the Drill as it relates to the far cortex is equal to where the end of the screw will be. Therefore, if the end of the Drill is 3mm beyond the far cortex, the end of the screw will also be 3mm beyond.**
- **The Screw Gauge, Short, is calibrated so that with the bend at the end pulled back flush with the far cortex, the screw tip will end 3mm beyond the far cortex (Fig. 21).**

When the Drill Sleeve is removed,the correct 4.0mm Locking Screw is inserted through the Tissue Protection Sleeve using the Screwdriver Shaft, Short (1806-0222) with the Teardrop Handle (702429, Fig. 22). The screw is near its' proper seating position when the groove around the shaft of the screwdriver is approaching the end of the Tissue Protection Sleeve.

Use image intensification to confirm screw position through the nail as well as screw length.

Repeat the locking procedure for the other statically positioned Locking Screw (Fig. 23).

Caution:

The coupling of Elastosil handles contains a mechanism with one or multiple ball bearings. In case of applied axial stress on the Elastosil handle, those components are pressed into the surrounding cylinder resulting in a complete blockage of the device and possible bending.

To avoid intra-operative complications and secure long-term functionality, we mandate that Elastosil handles be used only for their intended use.

DO NOT HIT any Elastosil handles.

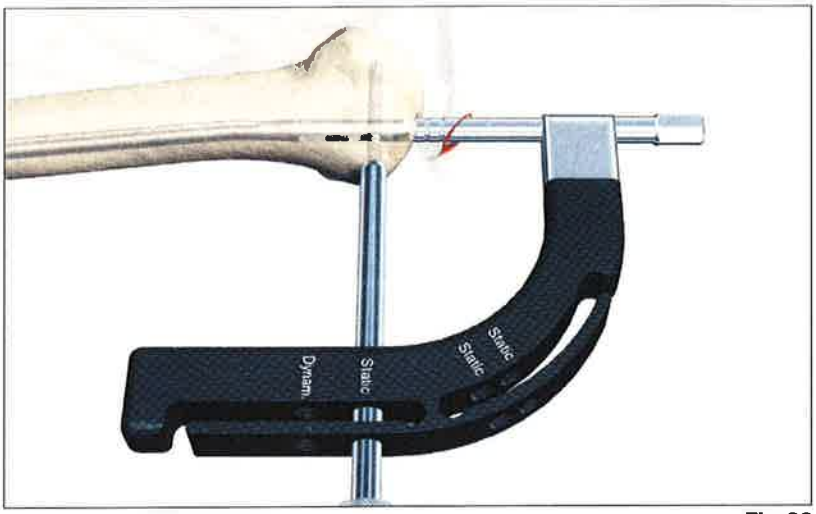


Fig. 22

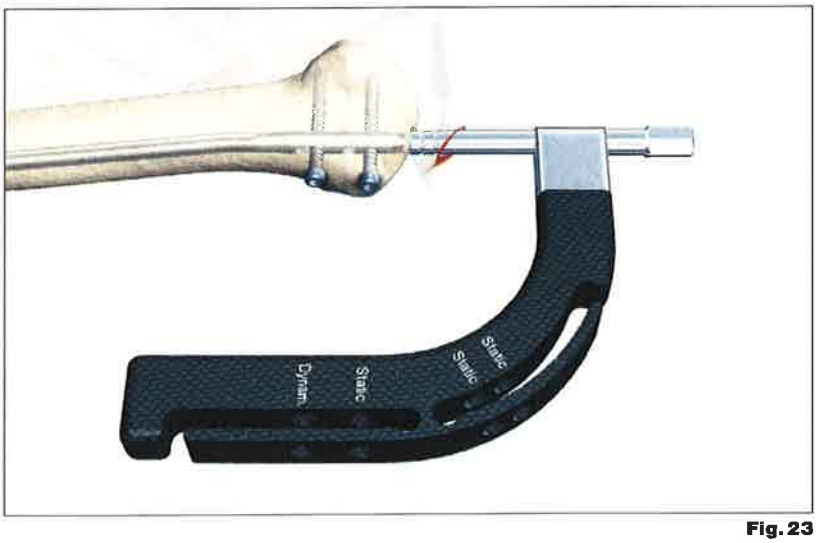


Fig. 23

Operative Technique – Antegrade Technique

Static Oblique Locking Mode

In cases that may be locked in the Static Oblique Locking Mode, place the assembly of the Tissue Protection Sleeve together with the Drill Sleeve and the Trocar through the Oblique static hole closest to the driving end of the nail (Fig. 24). Refer to the procedure for Locking Screw insertion.

The second Fully Threaded Locking Screw is inserted through the static hole (Fig. 25) next to the first hole, and placed in an oblique manner through the oblong hole of the nail (Fig. 26).

Confirm screw position and screw length with image intensification.

Washer

The Washer, either Rectangular or Round, may be used in cases of osteoporotic bone to bridge the bone gap and allow for enhanced purchase of the Locking Screw (Fig. 27).

Fig. 27

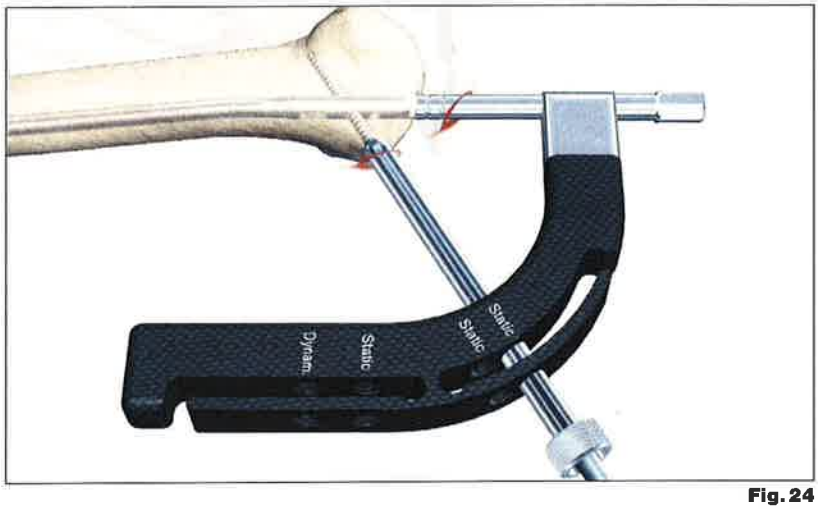


Fig. 24

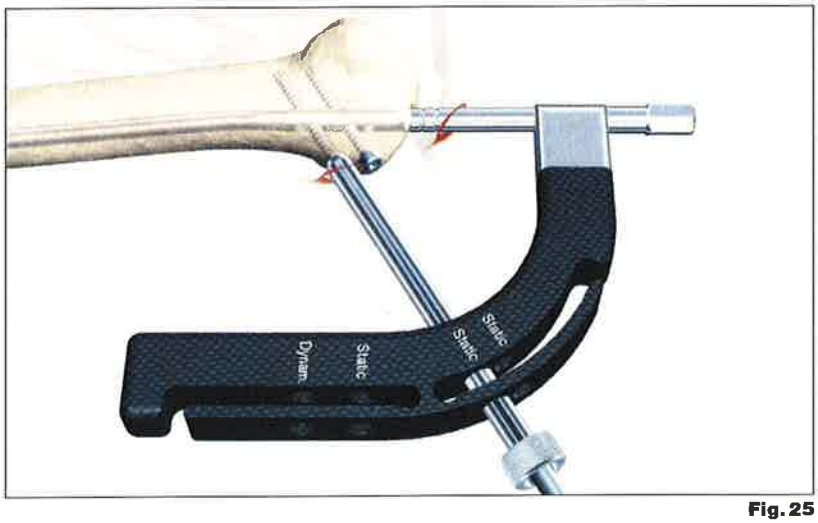


Fig. 25

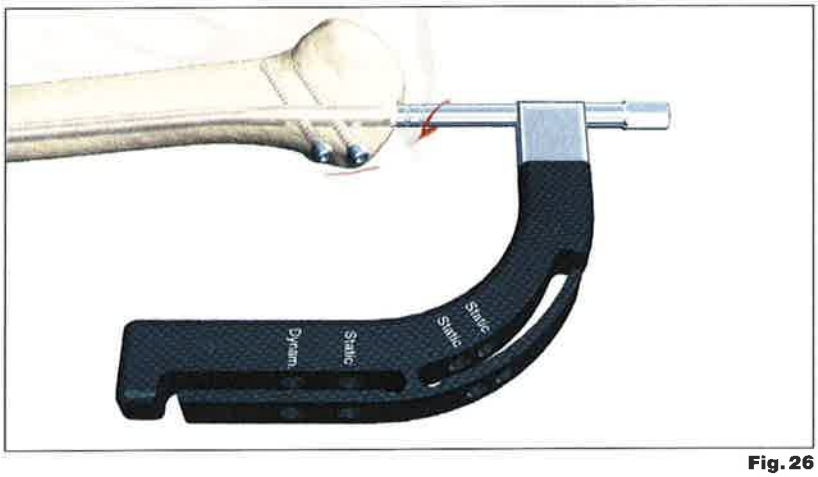


Fig. 26

Freehand Distal Locking

The freehand technique is used to insert Locking Screws into both the A/P and M/L holes in the nail. Rotational alignment must be checked prior to distal locking.

Multiple locking techniques and radiolucent drill devices are available for freehand locking. The critical step with any freehand locking technique, proximal or distal, is to visualize a perfectly round locking hole with the C-Arm.

Caution:

In order to avoid damage to the neurovascular structure, a limited open approach should be considered.

The center-tipped Ø3.5×230mm Drill (1806-3540S), or the optional Ø3.5×130mm Drill (1806-3550S), is held at an oblique angle to the center of the locking hole (Fig. 28 and 29). Upon X-Ray verification, the Drill is placed perpendicular to the nail and drilled through the anterior cortex. Confirm these views in both the A/P and M/L planes by X-Ray.

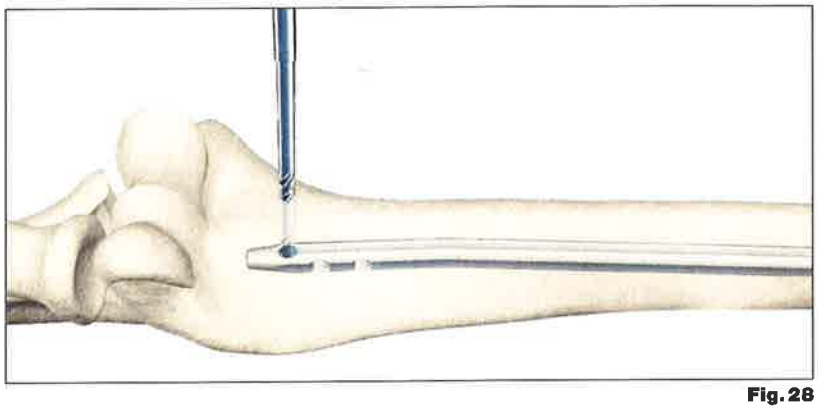


Fig. 28

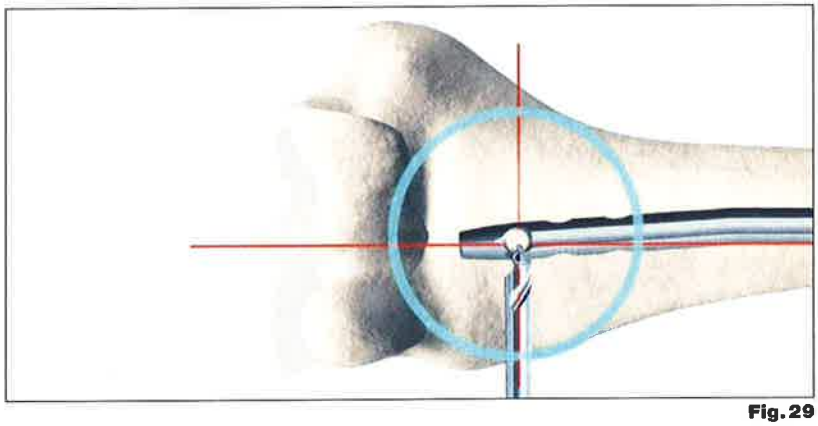


Fig. 29

Operative Technique – Antegrade Technique

After drilling both cortices, the screw length may be read directly off of the Screw Scale, Short (1806-0360) at the orange color coded ring on the center-tipped Drill (Fig. 30). As with proximal locking (Fig.21, p.19), the position of the end of the drill is equal to the end of the screw as they relate to the far cortex.

Routine Locking Screw insertion is employed with the assembled Short Screwdriver Shaft and the Teardrop Handle.

If possible, the distal humerus should be locked with two Fully Threaded Locking Screws. Additional locking of the M/L hole(s) is possible if the image intensifier can be adjusted (Fig. 31).

Note:

Use image intensification to confirm screw position through the nail as well as screw length.

Alternatively, the Screw Gauge can be used to measure the screw length.

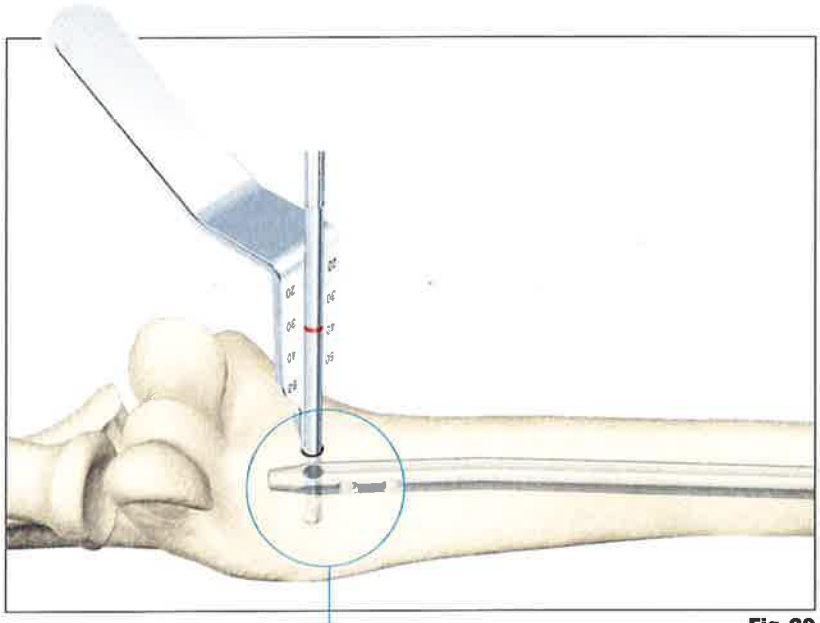


Fig. 30

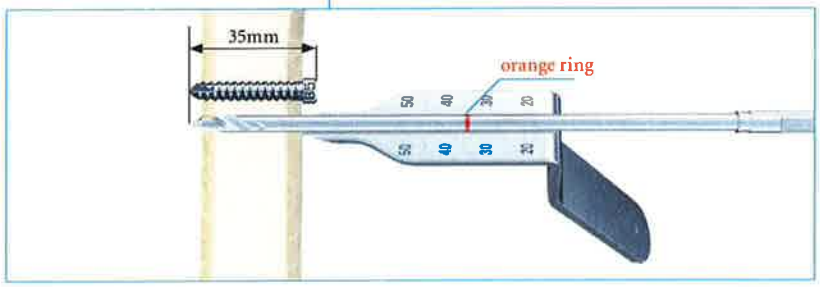


Fig. 30a

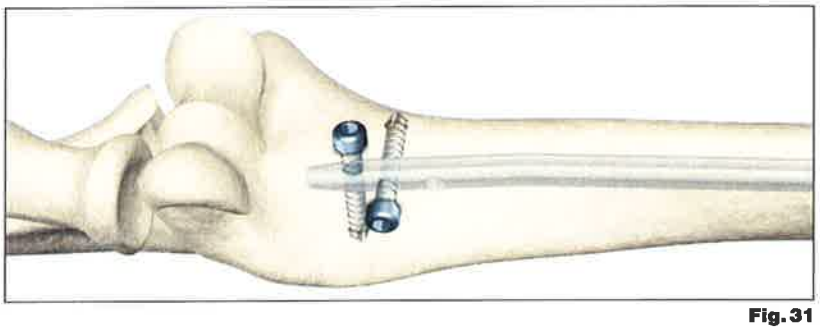


Fig. 31

End Cap Insertion

After removal of the Target Device, an End Cap is used to reduce the potential for bony ingrowth into the proximal threads of the nail.

End Caps are available in six sizes (Fig. 32).

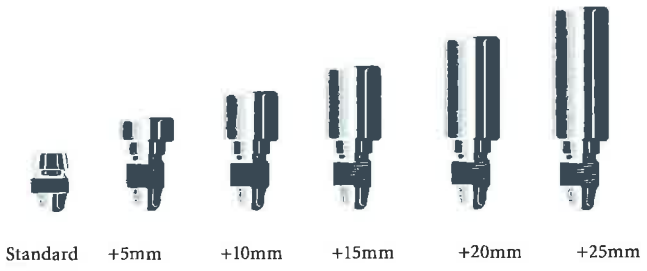


Fig. 32

The End Cap is inserted with the Short Screwdriver Shaft assembled on the Teardrop Handle after intra-operative radiographs show satisfactory reduction and hardware implantation (Fig. 33). Fully seat the End Cap to minimize the potential for loosening.

Caution:

To avoid impingement, carefully select the length of the End Cap.

Close the wound using standard technique.

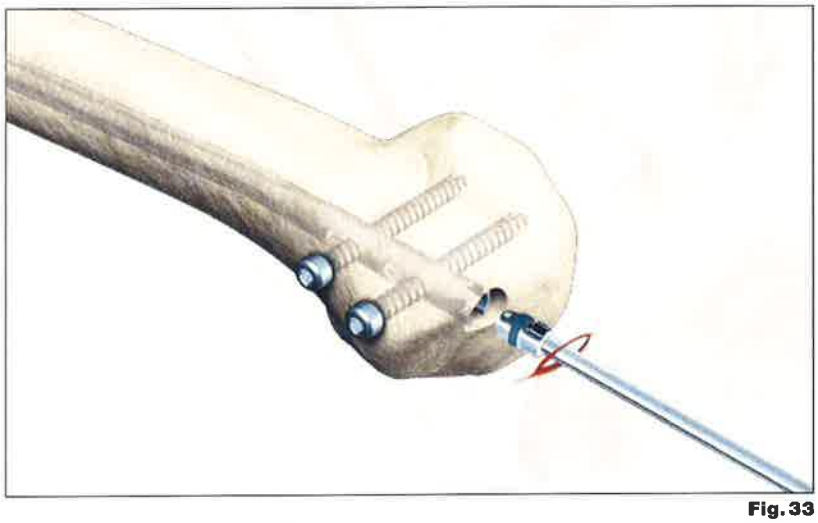


Fig. 33

Dynamic Locking Mode

When the fracture profile permits, controlled dynamic locking may be utilized for transverse or axially stable fractures.

Antegrade dynamization is performed by statically locking the nail distally.

The guided Partially Threaded Locking Screw (Shaft Screw) is then placed in the dynamic position of the oblong hole. This allows the nail to move, and the fracture to settle while torsional stability is maintained (Fig. 34).

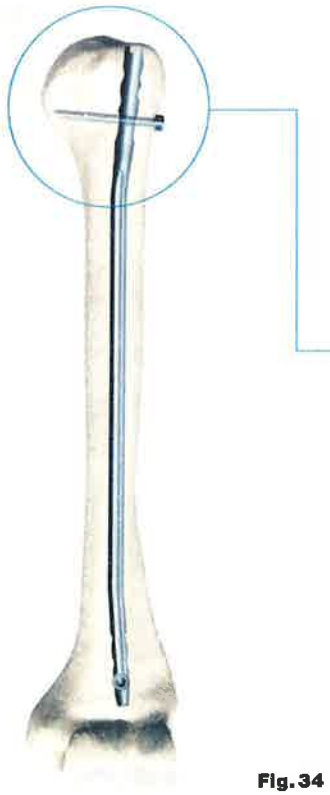


Fig. 34

Apposition/Compression Locking Mode

In transverse or axially stable fracture patterns, active apposition/compression increases fracture stability and enhances fracture healing. The antegrade T2 Humeral Nail provides the option to treat a humerus fracture with active mechanical apposition/compression prior to leaving the operating room.

Note:

Distal freehand static locking must be performed prior to applying active, controlled apposition/compression to the fracture site.

If active apposition/compression is required, a Partially Threaded Locking Screw (Shaft Screw) is inserted via the Target Device in the dynamic position of the oblong hole. This will allow for a maximum of 6mm of active, controlled apposition/compression. In order to insert the Partially Threaded Locking Screw (Shaft Screw), drill both cortices with the Ø3.5×230mm Drill (1806-3540S). Next, the near cortex ONLY is overdrilled with the Ø4.0×180mm Drill (1806-4000S).

Note:

After the opposite cortex is drilled with the Ø3.5×230mm drill, the correct screw length can be read directly off of the calibrated Drill at the end of the Drill Sleeve.

After the Partially Threaded Locking Screw (Shaft Screw) is inserted, the Nail Holding Screw is removed, leaving the insertion post intact with the nail (Fig. 35). This will act as a guide for the Compression Screw. The Compression Screw with the Compression Screwdriver Shaft (1806-0263) assembled on the Teardrop Handle is inserted through the insertion post (Fig. 36).

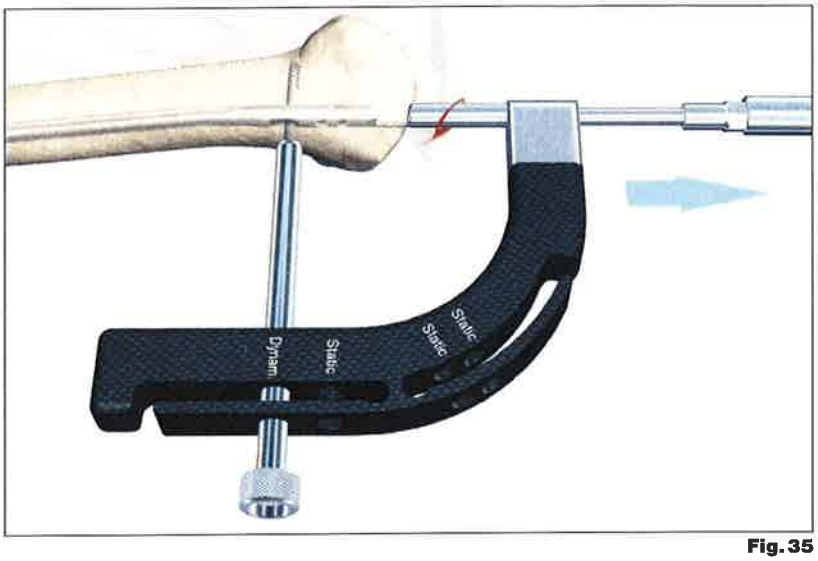


Fig. 35

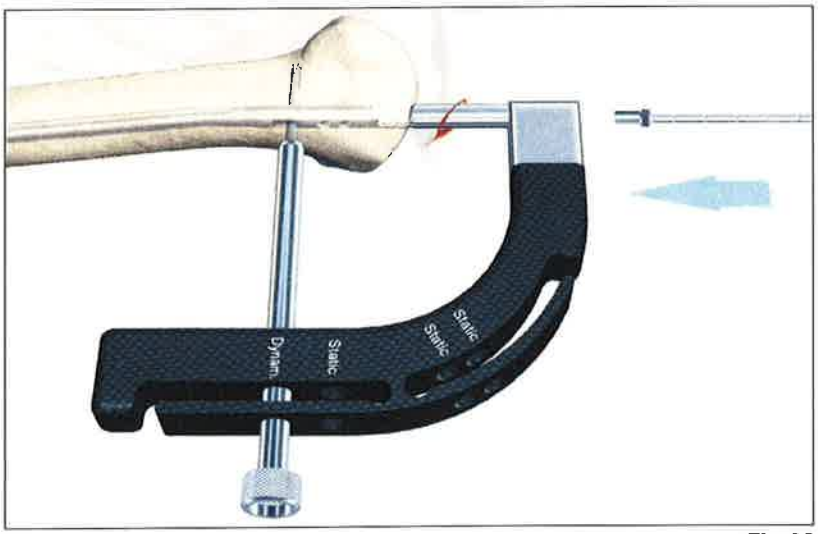


Fig. 36

Operative Technique – Antegrade Technique

Note:

It may be easier to "insert" the Compression Screw prior to fully seating the nail. Once the nail tip has cleared the fracture site, the Guide Wire (if used) is withdrawn. With the proximal portion of the nail not fully seated and extending out of the bone, the Advanced Compression Screw is inserted. Care should be taken that the shaft of the Compression Screw does not extend into the area of the oblong hole.

The Short Tissue Protection Sleeve is removed and the Compression Screw is gently tightened utilizing the two-finger technique (Fig. 37). As the Compression Screw is advanced against the 4.0mm Partially Threaded Locking Screw (Shaft Screw), it draws the distal fracture segment towards the fracture site, employing active apposition/compression (Fig. 38). Image intensification will enable the surgeon to visualize active apposition/compression. Some bending of the transverse Partially Threaded Locking Screw (Shaft Screw) may be seen.

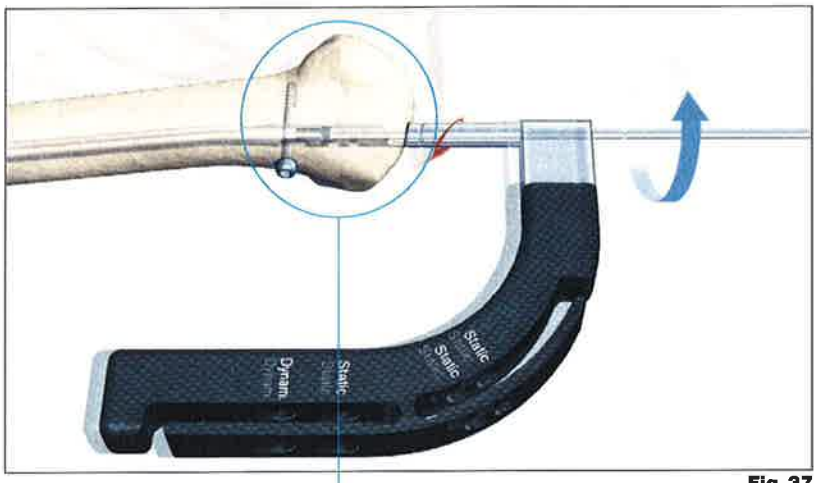


Fig. 37

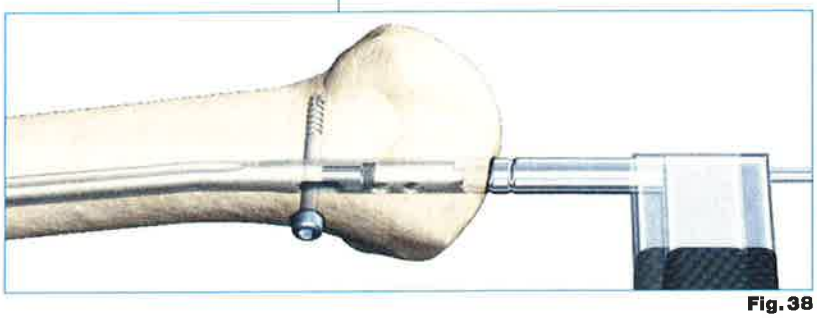


Fig. 38

Note:

- **Apposition/compression must be carried out under X-Ray control. Over-compression may cause the nail or the Partially Threaded Locking Screw (Shaft Screw) to fail.**
- **When compressing the nail, the implant must be inserted a safe distance from the entry point to accommodate for the 6mm of active compression. The three grooves on the insertion post are designed to help attain accurate insertion depth of the implant.**

Advanced Locking Mode

In order to achieve additional fixation and to reduce the load on the Partially Threaded Locking Screw (Shaft Screw), the design of the T2 Humeral Nail provides the opportunity to insert a Fully Threaded Locking Screw in the other transverse hole at the driving end of the nail after apposition/compression is utilized.

Prior to guided locking via the Target Device, the Nail Holding Screw must be tightened using the Insertion Wrench.

Fix the Advanced Compression Screw on the self-retaining Compression Screwdriver Shaft. Remove the Nail Holding Screw leaving the Target Device in place (Fig. 39). Advance the Compression Screw through the Target Device until the desired amount of compression is achieved. Visualize depth of insertion with the aid of flouroscopy (Fig. 40).

Note:

As previously described, it may be easier to insert the Compression Screw prior to fully seating the nail.

To reattach the Target Device to the nail, detach the Teardrop Handle from the Compression Screwdriver Shaft and screw the Nail Holding Screw over the Compression Screwdriver Shaft into its required position.

To insert the second transverse Fully Threaded Locking Screw, follow the locking procedure for static locking (Fig. 41).

Finally, an End Cap should be inserted, as shown on page 24.

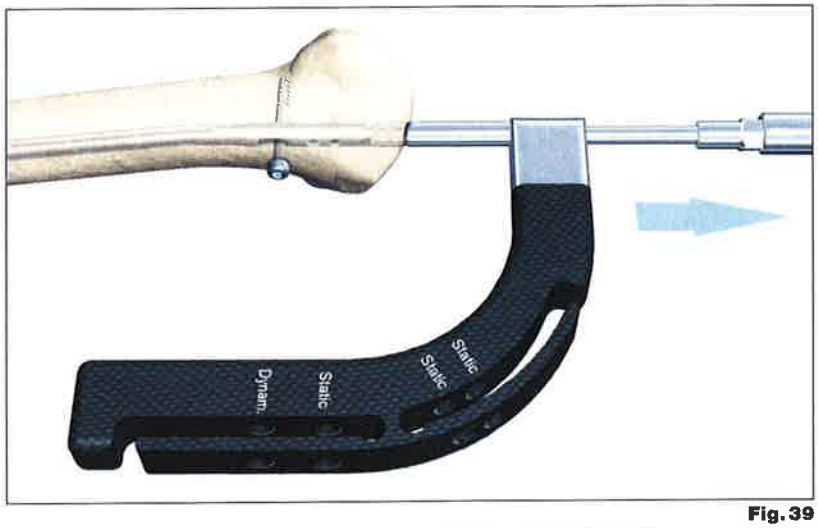


Fig. 39

Fig. 40

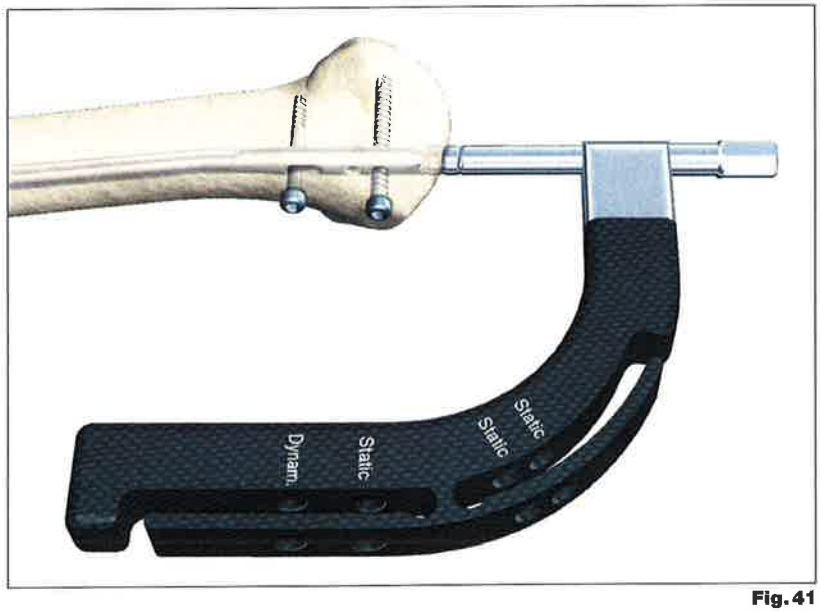


Fig. 41

Nail Removal

Nail removal is an elective procedure. If used, first remove the End Cap with the Short Screwdriver Shaft and the Teardrop Handle (Fig. 42).
If Advanced Locking Mode was utilized, the most proximal screw is extracted first, allowing access to the compression screw. Next, disengage the Advanced Compression Screw from the Fully Threaded Locking Screw (Shaft Screw) by turning the Compression Screwdriver one full turn in a counter-clockwise direction (Fig. 43).

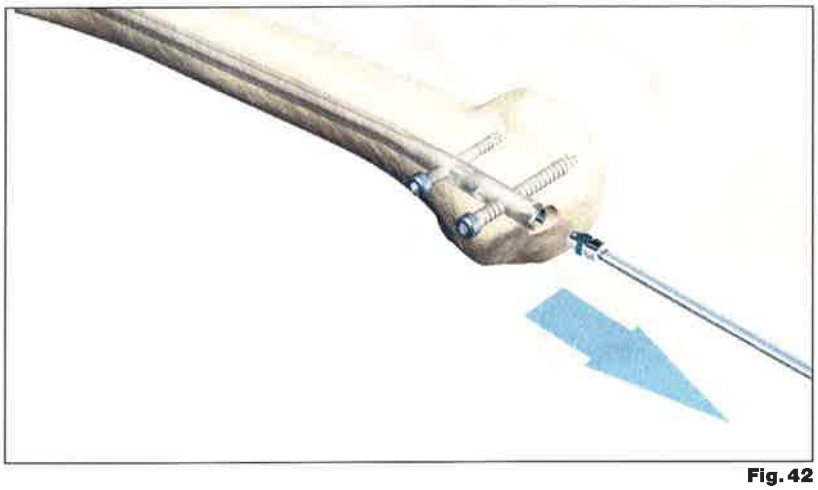


Fig. 42

Note:

There is no need to attempt to remove the Advanced Compression Screw from the nail, which with the nail implanted, may be difficult.

The Universal Rod, Short is inserted into the driving end of the nail before all Locking Screws are removed with the Short Screwdriver Shaft and the Teardrop Handle (Fig. 43).

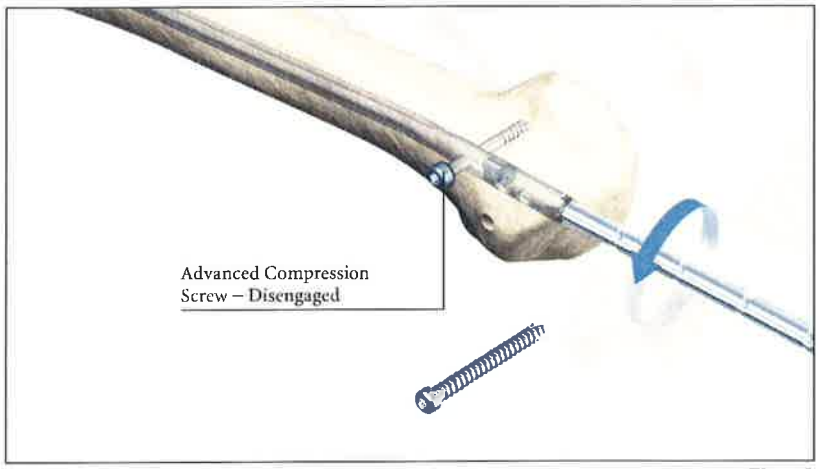


Fig. 43

Note:

Attaching of the Universal Rod to the nail first will reduce the potential for nail migration, then the locking screws may be removed safely.

The Slotted Hammer is used to extract the nail in a controlled manner (Fig. 44).

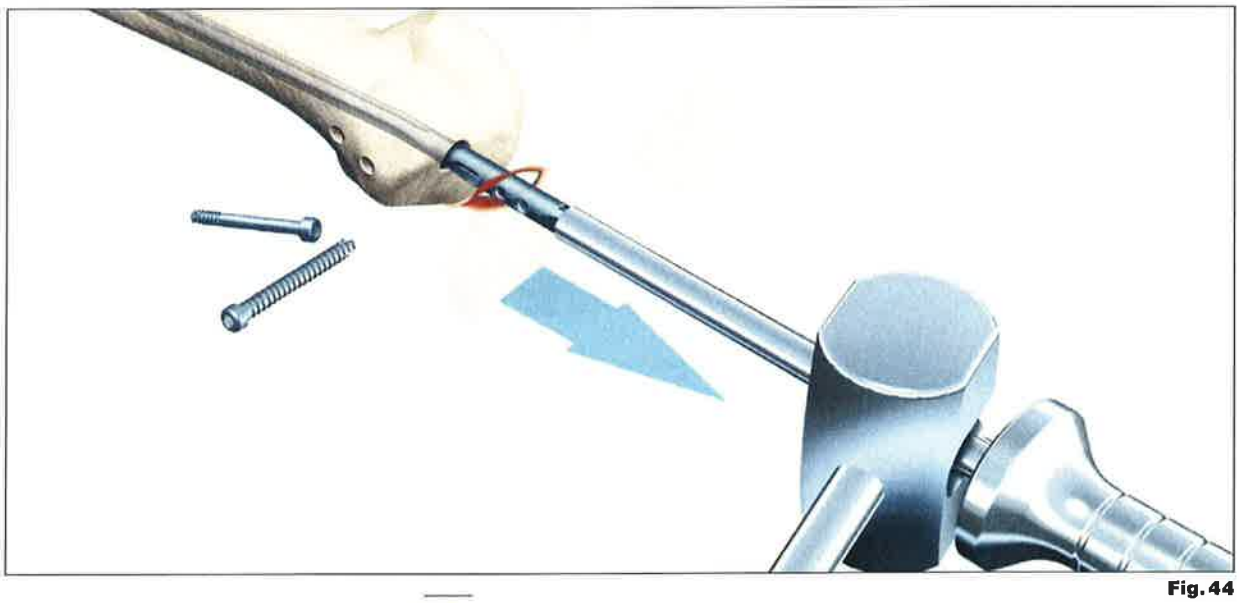


Fig. 44

Operative Technique – Retrograde Technique

Patient Positioning

The patient is placed on a radiolucent table in the prone position or lateral decubitus position. The affected arm is supported on an arm board or hand table. The shoulder is in 90° abduction, the elbow joint flexed also in a 90° position. In this position, fractures can be reduced in correct rotation.

Patient positioning should be checked to ensure that imaging of the entry site at the proximal humerus is possible. This allows the elbow to be hyper flexed to accommodate insertion of the implant parallel to the humerus.

Incision

A posterior approach is used to access the distal humerus. Starting at the tip of the olecranon, a 6cm incision is made in a proximal direction. The triceps tendon is split and muscle tissue is bluntly dissected and retracted until the upper edge of the olecranon fossa is displayed.

The distal insertion point for the nail is one centimeter above the olecranon fossa. The Insertion Site Template (703117) may be used to help determine the appropriate insertion site (Fig. 45). The medullary canal is opened using the Drill Ø3.5 × 130mm (1806-3550S) by drilling a set of linear holes (Fig. 46). The holes are then joined with the Self-guiding Rigid Reamer (703125) (Fig. 47).

Note:

The drill guide slots of the retrograde Insertion Site Template (703117), must be centered and parallel to the medullary canal (long axis of the humerus).

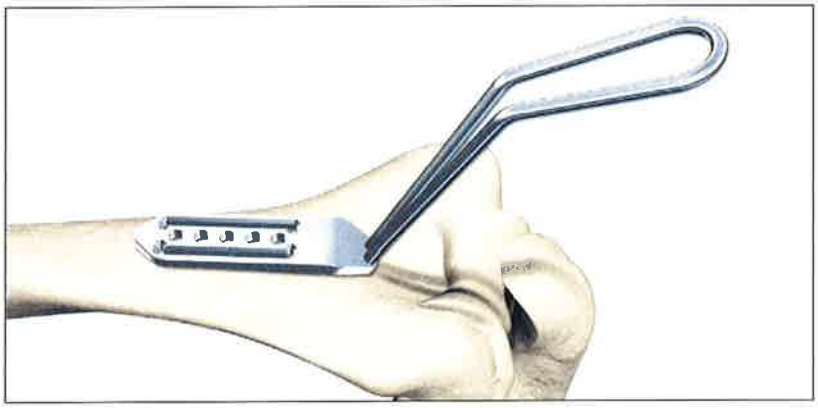


Fig. 45

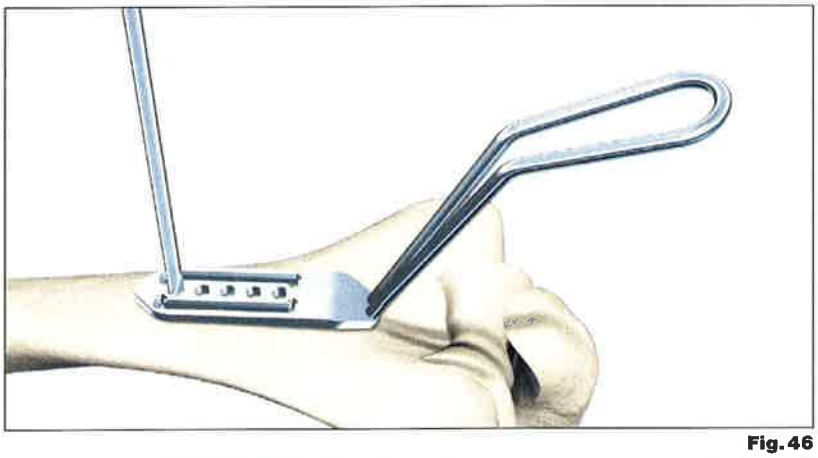


Fig. 46

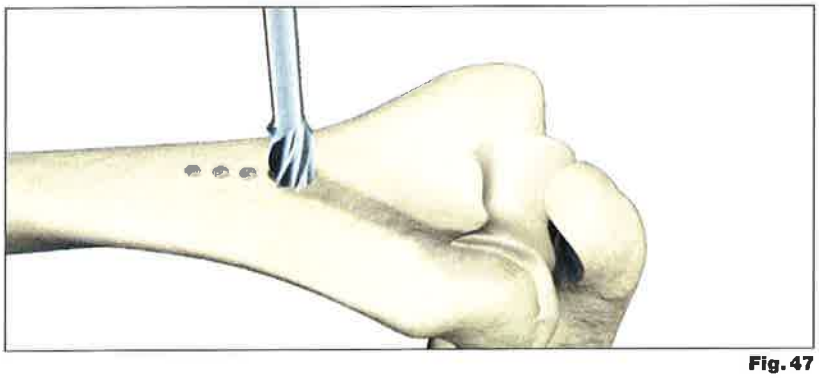


Fig. 47

Operative Technique – Retrograde Technique

Entry Point

Final insertion site preparation is performed with the Conical Rigid Reamer (703126) to create a longitu-dinal oval cortical hole at least 3cm in length and 1cm in width (Fig. 49).

The cortical bone is removed distally to the level of the olecranon fossa with the rigid reamers or small rongeur.

Caution:

Although the tip of the nail has a 4 degree bend that facilitates distal nail insertion, high compressive forces during nail insertion can result in fractures of the distal humerus if the insertion opening is too short or too steep.

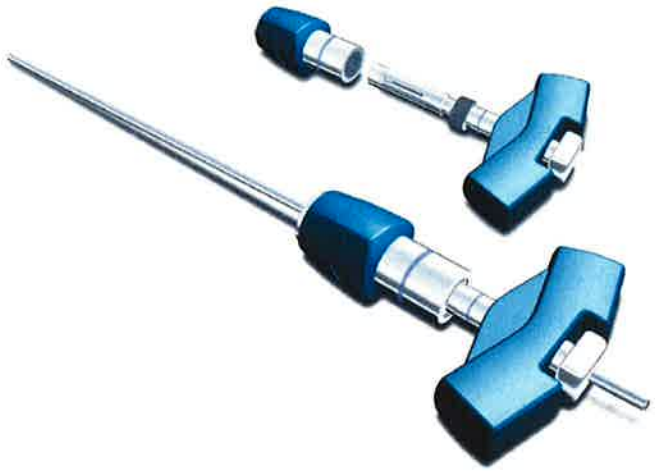


Fig. 48

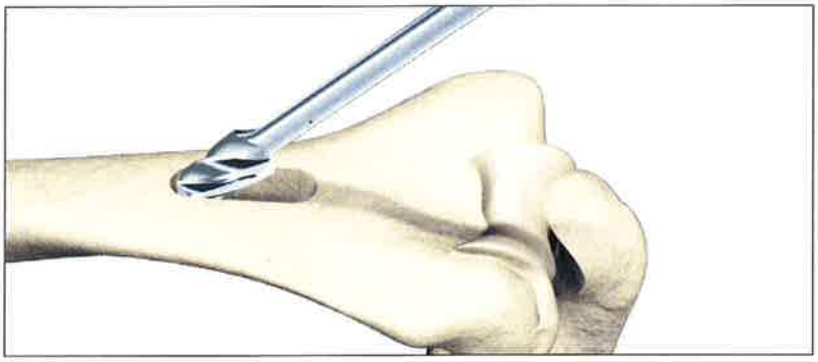


Fig. 49

Unreamed Technique

The T2 Humeral Nail is cannulated, and may be introduced in an un-reamed fashion over a Smooth Tip Guide Wire. This simplifies fracture reduction and reduces the risk of iatro-genic distal fractures caused by trying to reduce the fracture with the nail.

The 2.2×800mm Smooth Tip Guide Wire (1806-0093S) is inserted under image control through the distal frag-ment and into the desired position within the proximal humerus using the Guide Wire Handle and Chuck (1806-1095 and 1806-1096) (Fig. 48 and 50).

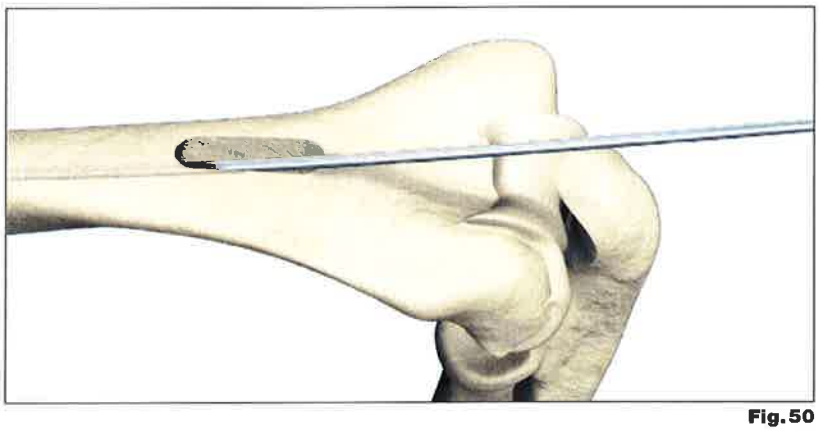


Fig. 50

The Reduction Rod (1806-0363) may be used as a fracture reduction tool to facilitate Guide Wire insertion (Fig. 51). The Guide Wire is advanced until the tip rests at the center of the humeral head. The Guide Wire should lie in the center of the metaphysis in both the A/P and Lateral views to help avoid offset positioning of the nail. The Guide Wire Handle is removed leaving the Guide Wire in place.

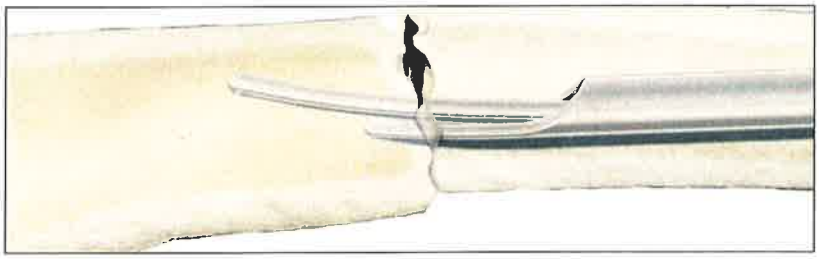


Fig. 51

Reamed Technique

For reamed techniques, the 2.5×800mm Ball Tip Guide Wire (1806-0083S) is inserted through the fracture site. The Reduction Rod or the Universal Rod, Short with the "optional" Reduction Spoon may be used as a fracture reduction tool to facilitate Guide Wire insertion across the fracture site (see Fig. 51).

Reaming is commenced in 0.5mm increments until cortical contact is appreciated. (Fig. 50). The final reamer should be 1mm–1.5mm larger than the diameter of the nail to be used.

The Guide Wire Pusher can be used to help keep the Guide Wire in position during reamer shaft extraction. The metal cavity at the end of the handle pushed on the end of the power tool facilitates to hold the Guide Wire in place when starting to pull the power tool. When close to the Guide Wire end place the Guide Wire Pusher with its funnel tip to the end of the power tool cannulation. While removing the power tool the Guide Wire Pusher will keep the Guide Wire in place (Fig. 53 and 54).

Note:

The driving end of the 7mm nail is always 8mm.

When reaming is complete, the Teflon Tube (1806-0073S) should be used to exchange the Ball Tip Guide Wire with the Smooth Tip Guide Wire for nail insertion.

Note:

Do not insert any T2 Humeral Nail over any Ball Tip Guide Wire.

An unreamed technique can be considered in cases, where the medullary canal has the appropriate diameter. In these cases, the nail can be introduced over the 2.2×800mm Smooth Tip Guide Wire (1806-0093S).

Note:

X-Ray Templates should be used pre-operatively to determine the canal size radiographically.

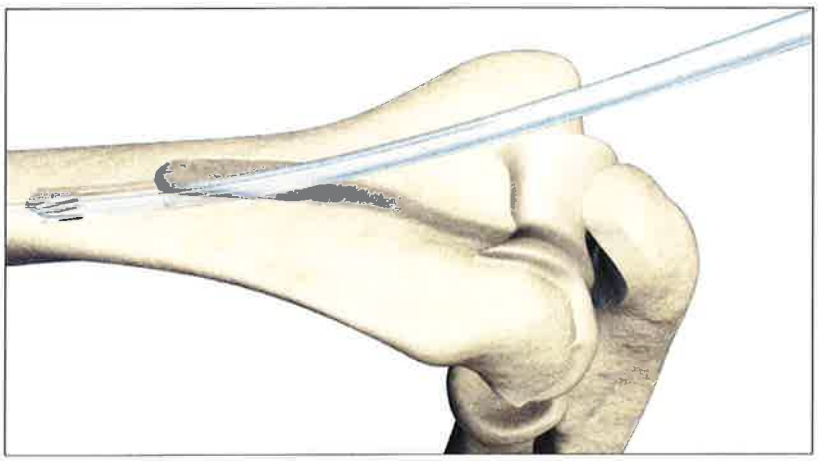


Fig. 52

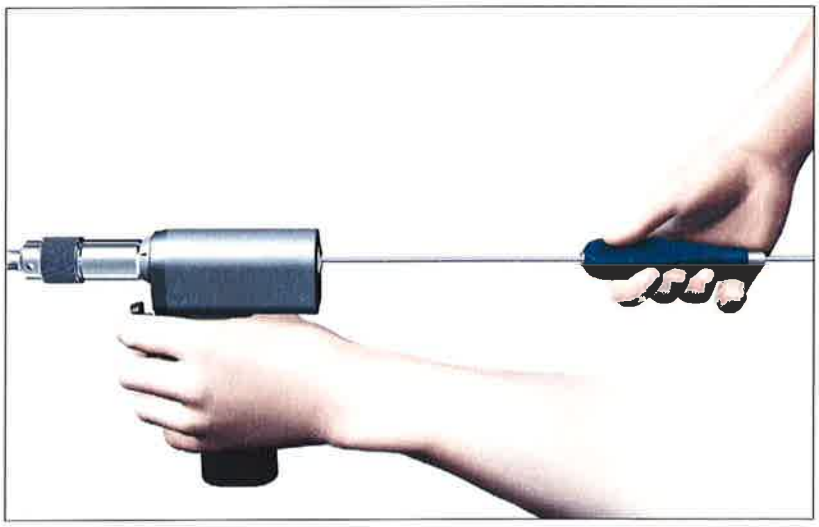


Fig. 53

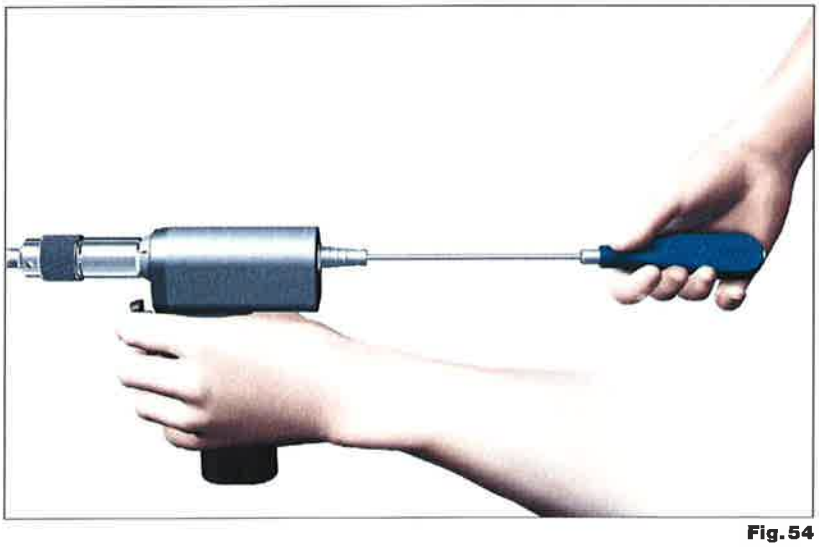


Fig. 54

Operative Technique – Retrograde Technique

Nail Selection

The X-Ray Template (1806-003) should be used preoperatively to determine canal size radiographically. This information may be utilized in conjunction with the clinical assessment of canal size as determined by the size of the last reamer used.

Diameter
The diameter of the selected nail should be 1mm smaller than the last reamer used.

Length
Nail length may be determined with the X-Ray Ruler (1806-0013) (Fig. 55). The Guide Wire Ruler (1806-0022) may be used by placing it on the Guide Wire and then reading the correct nail length at the end of the Guide Wire on the Guide Wire Ruler (Fig. 56). Confirm the position of the tip of the Guide Wire prior to measurement.

Note:
If the fracture is suitable for apposition/compression, the implant selected should be 6–10mm shorter than measured to help avoid migration of the nail beyond the insertion site.

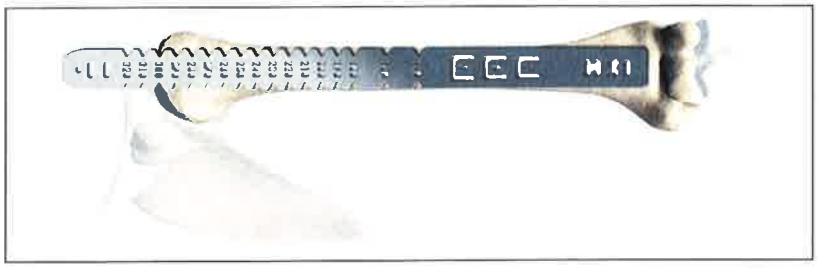


Fig. 55

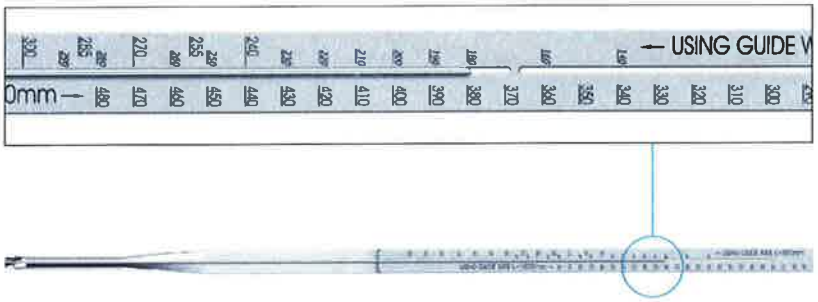


Fig. 56

The Guide Wire Ruler can be easily folded and unfolded.

Nail Insertion

The selected nail is assembled onto the Target Device (1806-0143) with the Nail Holding Screw (1806-0163). Tighten the Nail Holding Screw with the Insertion Wrench (1806-0135) securely so that it does not loosen during nail insertion (Fig. 57).

Fig. 57

Operative Technique – Retrograde Technique

Note:

Prior to nail insertion please check correct alignment by inserting a drill bit through the assembled Tissue Protection and Drill Sleeve placed in the required holes of the targeting device.

Upon completion of reaming and Guide Wire exchange, the appropriate size nail is ready for insertion and is advanced through the entry point past the fracture site to the appropriate level.

Gentle rotation of the nail may be necessary to start nail insertion. The nail should be advanced with manual pressure (Fig. 58). Aggressive use of the slotted hammer can result in additional fractures. If the nail does not advance easily, a check with image intensification should be made to see if the nail angle is too steep and the nail is impinging on the anterior cortex. In this case, it may be necessary to further widen the insertion opening.

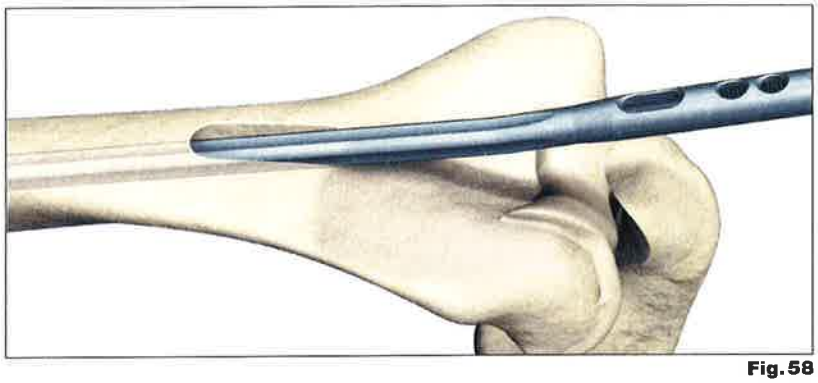


Fig. 58

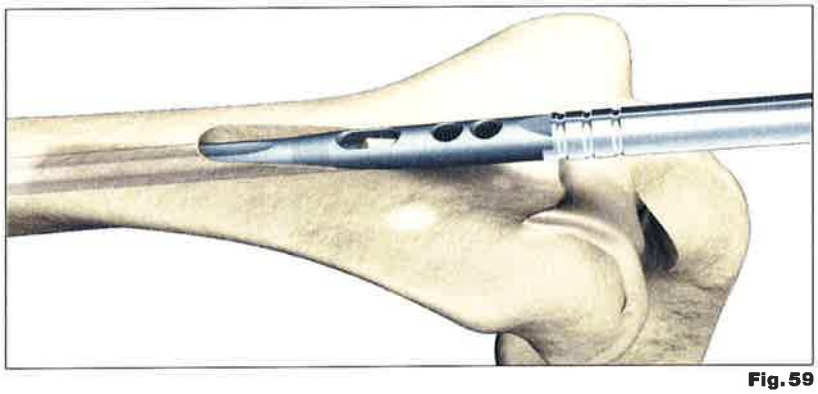


Fig. 59

Note:

A chamfer is located on the driving end of the nail to denote the end under X-Ray. Three circumferential grooves are located on the insertion post at 2mm, 6mm, and 10mm from the driving end of the nail (Fig. 59). Depth of insertion may be visualized with the aid of fluoroscopy.

The 3×285mm K-Wire may be inserted through the Target Device which identifies the junction of the nail and insertion post.

Insertion of the nail into the fracture zone should be monitored under image intensification.

The nail can be inserted over the Smooth Tip Guide Wire by gentle impaction on the Nail Holding Screw/ Insertion Wrench assembly (Fig. 60) or the Nail Holding Screw/Strike Plate assembly (Fig. 61).

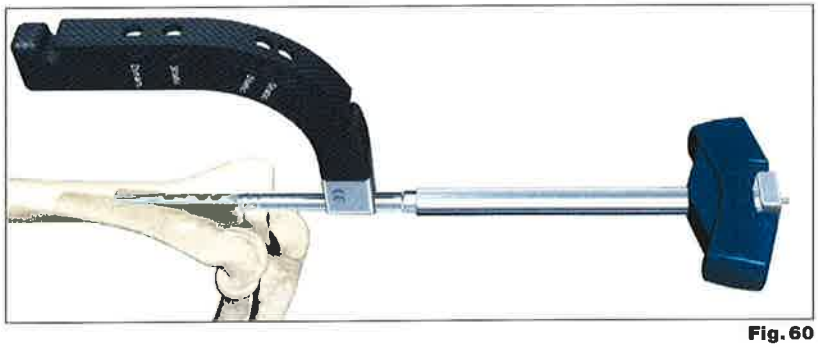


Fig. 60

Operative Technique – Retrograde Technique

Repositioning may be carried out either by hand or by attaching the Universal Rod, Short to the Nail Holding Screw. The slotted hammer may be used to reposition the nail smoothly (Fig. 62). DO NOT hit on the Target Device.

When locking the retrograde nail in the Static Mode, the nail is countersunk a minimum of 6mm below the surface. When the implant is inserted in the Dynamic Mode, with active apposition/compression, or in the Advanced Locking Mode, the recommended insertion depth is 10mm.

Note:

Remove the Guide Wire prior to drilling and inserting the Locking Screws.

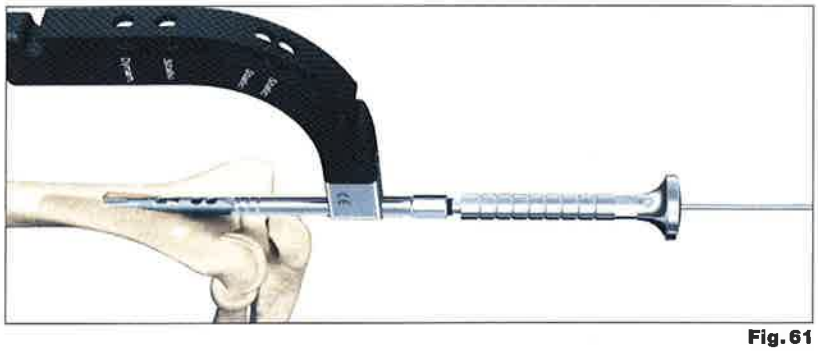


Fig. 61

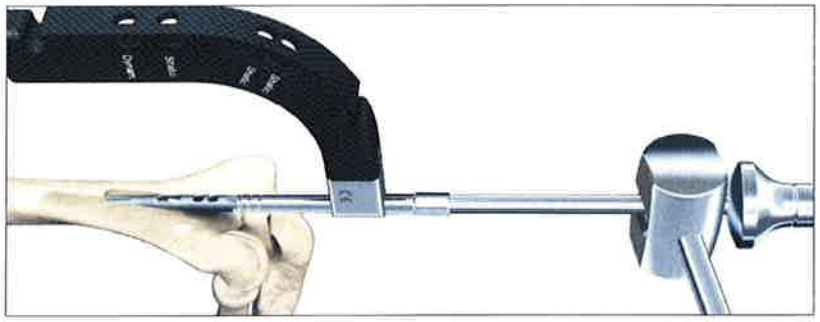


Fig. 62

Guided Locking Mode (via Target Device)

Prior to guided locking via the Target Device, the Nail Holding Screw must be firmly tightened using the Insertion Wrench, to ensure that the nail isin correct alignment with the Target Device.

The Target Device is designed to provide four options for guided locking (Fig. 63.1–63.4).

In Static Oblique Locking Mode, the two static holes closest to the end of the nail may be used for static oblique (30°) locking (Fig. 63.1).
1. Static
2. Static

Fig. 63.1

In Static Transverse Locking Mode, the next static hole and the dynamic hole are used for static transverse locking (Fig. 63.2).
3. Static
4. Dynamic

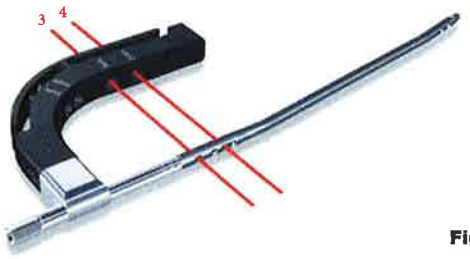


Fig. 63.2

In controlled Dynamic Mode, and/or controlled Apposition/Compression Mode, the dynamic hole is required (Fig. 63.3).
4. Dynamic

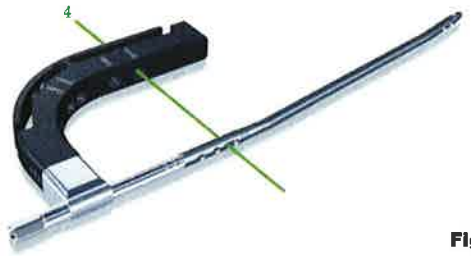


Fig. 63.3

In Advanced Locking Mode, the dynamic hole is required. After utilizing compression with the Advanced Compression Screw, the static hole is used (Fig. 63.4).
4. Dynamic
3. Static

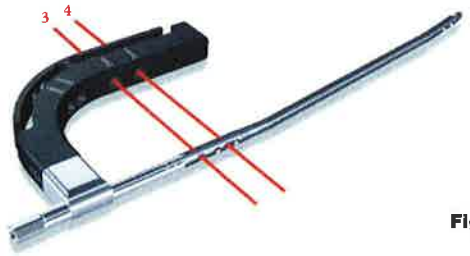


Fig. 63.4

The Tissue Protection Sleeve, Short (1806-0180) together with the Drill Sleeve, Short (1806-0210) and the Trocar, Short (1806-0310) are inserted into the Target Device by pressing the safety clip (Fig. 64). The friction lock mechanism is designed to keep the sleeve in place and prevent it from falling out. It is designed to also keep the sleeve from sliding during screw measurement. To release the Tissue Protection Sleeve, the safety clip must be pressed again (Fig. 65).

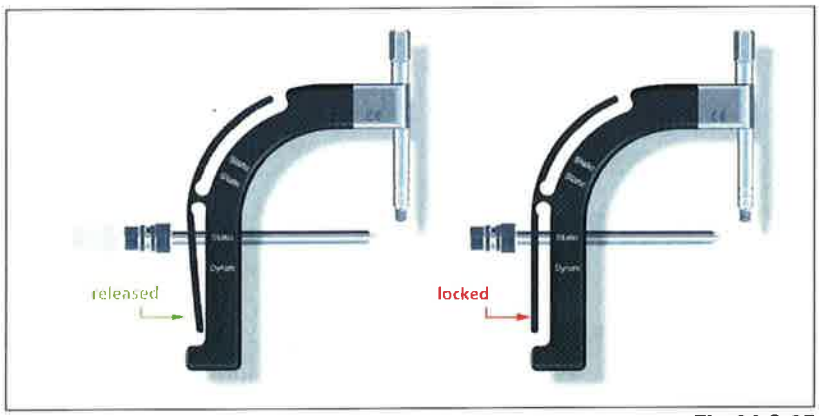


Fig. 64 & 65

Static Locking Mode

Static Transverse Locking Mode

In unstable or comminuted fractures, the nail should be used as a standard interlocking nail. Static locking will help maintain the length of the nail and the rotational stability of the fracture.

The Short Tissue Protection Sleeve together with the Short Drill Sleeve and the Short Trocar are positioned through the static locking hole on the Target Device. A small skin incision is made and the assembly is pushed through, until it is in contact with the posterior cortex of the humerus.

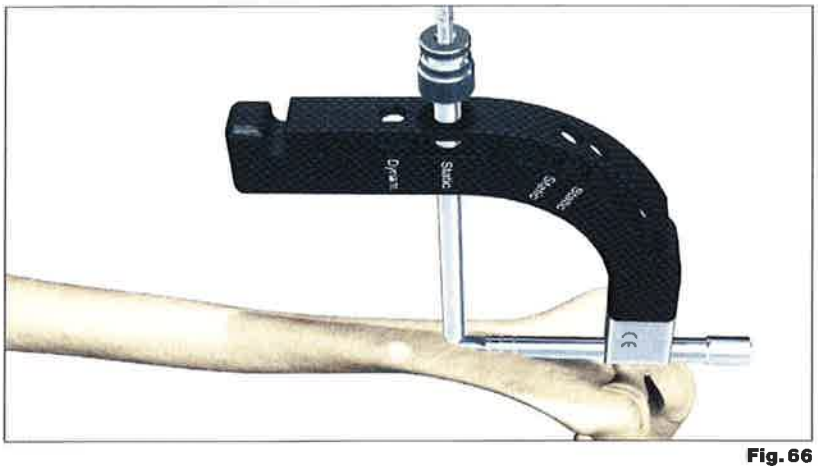


Fig. 66

Note:

Especially in the proximal humerus, use image intensification to help ensure the Tissue Protection sleeve is flush with the cortex or you could lose 1–2mm of screw measurement accuracy.

The Trocar is removed, while the Tissue Protection Sleeve and the Drill Sleeve remain in position.

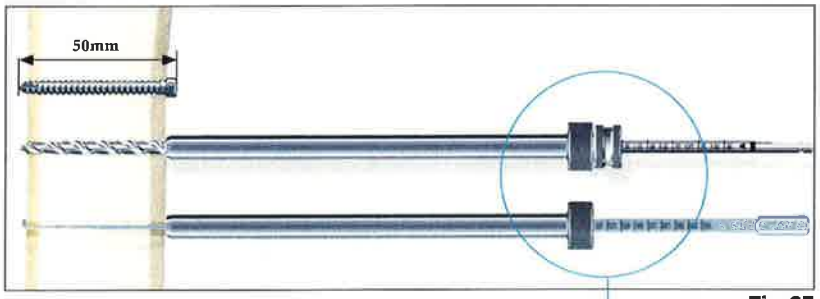


Fig. 67

For accurate drilling and easy determination of screw length, use the center-tipped Ø3.5×230mm calibrated Drill (1806-3540S). The Drill is forwarded through the Drill Sleeve and pushed onto the cortex.

Caution:

Make sure the Tissue Protection Sleeve/Drill Sleeve Assembly is seated on bone prior to selecting final screw length.

After drilling both cortices, the screw length may be read directly off of the calibrated Drill at the end of the Drill Sleeve (Fig. 66 and 67).

Note:

The position of the end of the Drill as it relates to the far cortex is equal to where the end of the screw will be. Therefore, if the end of the Drill is 3mm beyond the far cortex, the end of the screw will also be 3mm beyond.

Operative Technique – Retrograde Technique

Note:

The Screw Gauge, Short, is calibrated so that with the bend at the end pulled back flush with the far cortex, the screw tip will end 3mm beyond the far cortex (Fig. 67)

When the Drill Sleeve is removed, the correct 4mm Locking Screw is inserted through the Tissue Protection Sleeve using the Short Screwdriver Shaft (1806-0222) with the Teardrop Handle (702429). The screw is driven through both cortices and is near its' proper seating position when the center of the groove around the shaft of the screwdriver is approaching the end of the Tissue Protection Sleeve (Fig. 68).

Use image intensification to confirm screw position through the nail as well as screw length. Repeat the locking procedure for the other statically positioned Locking Screw (Fig. 69).

Note:

Only the Static Transverse Locking Option allows the nail to be easily compressed in a secondary procedure. The static Locking Screw closest to the driving end of the nail may be removed and the Compression Screw can be inserted into the nail.

Caution:

The coupling of Elastosil handles contains a mechanism with one or multiple ball bearings. In case of applied axial stress on the Elastosil handle, those components are pressed into the surrounding cylinder resulting in a complete blockage of the device and possible bending.
To avoid intra-operative complications and secure long-term functionality, we mandate that Elastosil handles be used only for their intended use. DO NOT HIT any Elastosil handles.

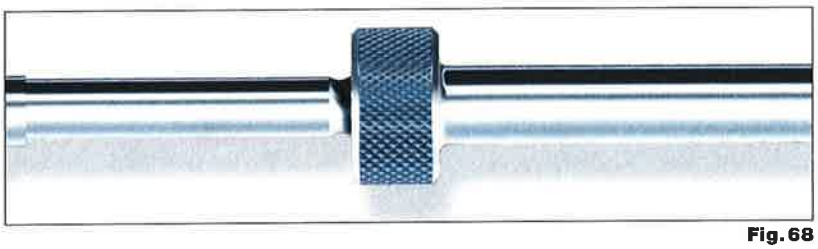


Fig. 68

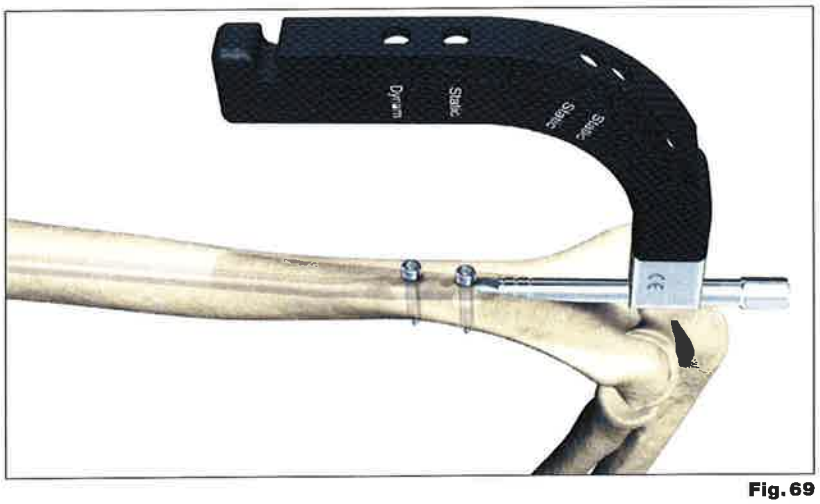


Fig. 69

Operative Technique – Retrograde Technique

Static Oblique Locking Mode

For the Static Oblique Locking Mode, place the assembly of Tissue Protection Sleeve together with the Drill Sleeve and the Trocar through the Static hole closest to the driving end of the nail. Refer to the procedure described for Locking Screw insertion (Fig. 70).

The second Fully Threaded Locking Screw is inserted through the Static hole next to the first hole and placed in an oblique manner through the oblong hole of the nail (Fig.71).

Confirm screw position and length with image intensification.

Washer

If the nail insertion opening is too long, or if osteoporotic bone is encountered, it may not be possible to achieve bicortical purchase for the most distal Fully Threaded Locking Screw. A Washer, either Rectangular or Round, may be used to bridge the bone gap and allow for enhanced purchase of the Locking Screw (Fig. 72).

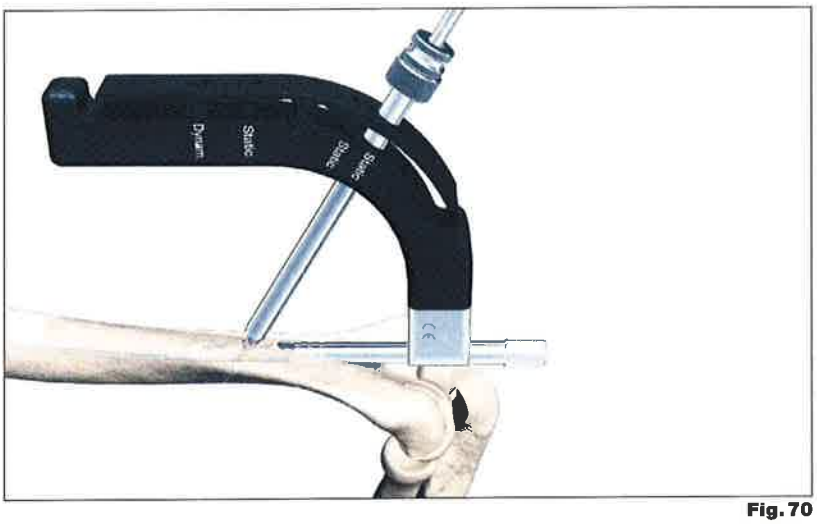


Fig. 70

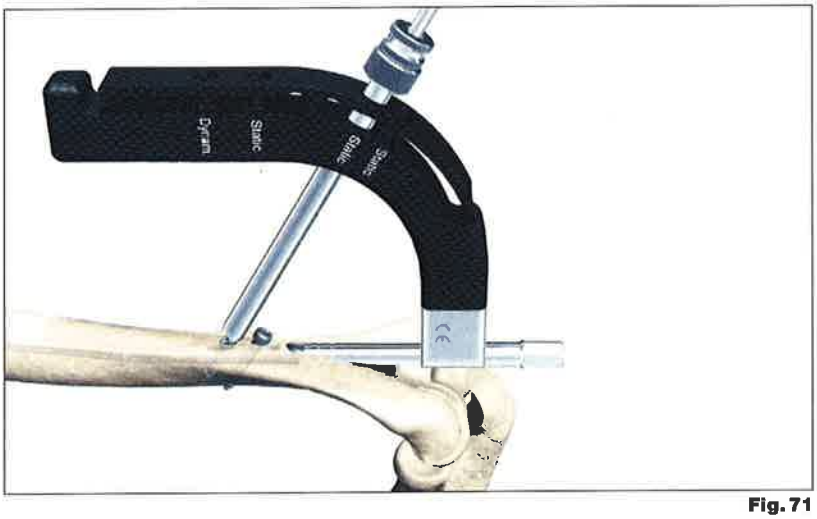


Fig. 71

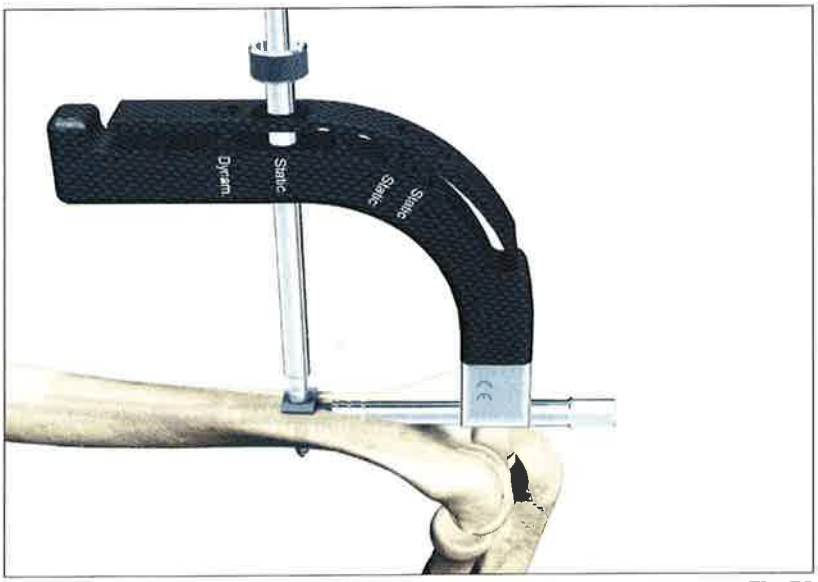


Fig. 72

Freehand Proximal Locking

The freehand technique is used to insert Locking Screws into both the A/P and M/L holes in the nail. Rotational alignment must be checked prior to locking the nail statically.

Multiple locking techniques and radiolucent drill devices are available for freehand locking. The critical step with any freehand locking technique, proximal or distal, is to visualize a perfectly round locking hole with the C-Arm.

The center-tipped Ø3.5×230mm Drill (1806-3540S), or the optional Ø3.5×130mm Drill (1806-3550S), is held at an oblique angle to the center of the locking hole (Fig. 73). Upon X-Ray verification, the Drill is placed perpendicular to the nail and drilled through the anterior cortex. Confirm these views in both the A/P and M/L planes by X-Ray.

After drilling both cortices, the screw length may be read directly off of the Screw Scale, Short (1806-0360) at the orange color coded ring on the center-tipped Drill (Fig. 74). As with distal locking (Fig. 67, p. 27), the position of the end of the drill is equal to the end of the screw as they relate to the far cortex.

Routine Locking Screw insertion is employed with the assembled Short Screwdriver Shaft and the Teardrop Handle.

If possible, the proximal humerus should be locked with two Fully Threaded Locking Screws (Fig. 75).

Note:

Use image intensification to confirm screw position within the nail as well as screw length.

Alternatively, the Screw Gauge can be used to measure the screw length.

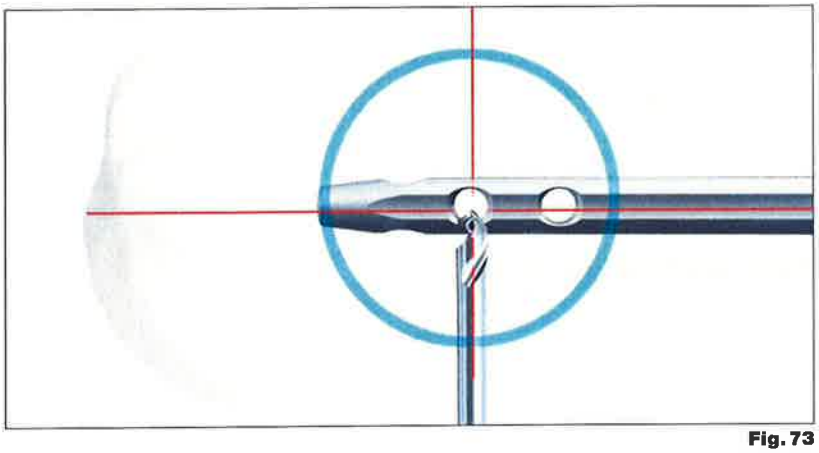


Fig. 73

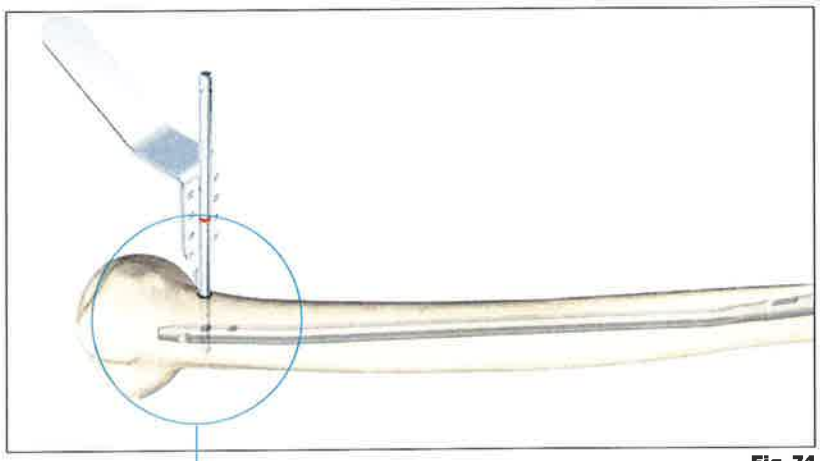


Fig. 74

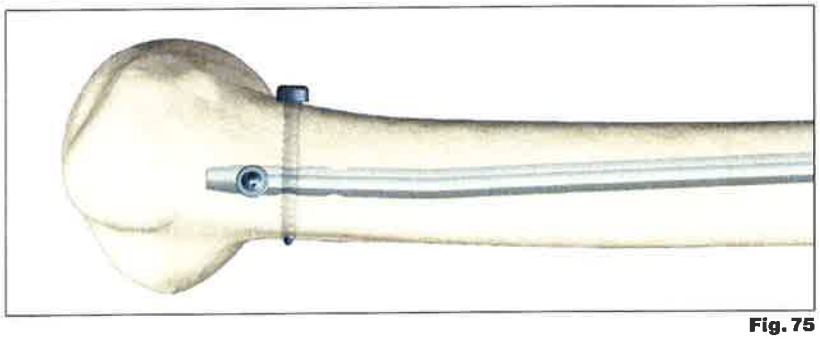


Fig. 75

End Cap Insertion

After removal of the Target Device, an End Cap is used to reduce the potential for bony ingrowth into the proximal threads of the nail.

End Caps are available in six sizes (Fig. 76).

Fig. 76

The End Cap is inserted with the Short Screwdriver Shaft assembled on the Teardrop Handle after intra-operative radiographs show satisfactory reduction and hardware implantation (Fig. 77). Fully seat the End Cap to minimize the potential for loosening.

Caution:

To avoid impingement, carefully select the length of the End Cap.

Close the wound using standard technique.

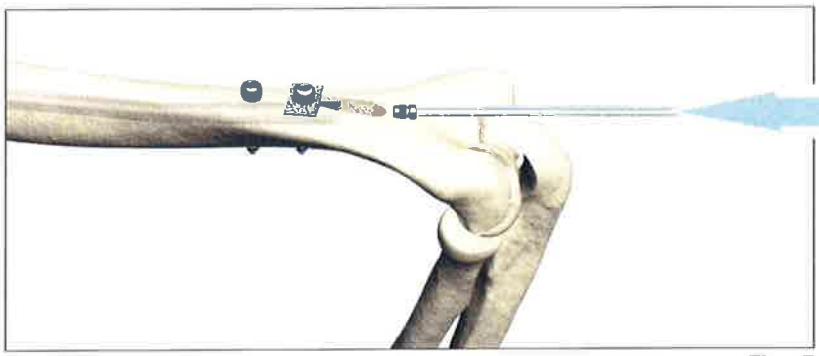


Fig. 77

Dynamic Locking Mode

Controlled dynamic locking may be utilized for transverse or axially stable fractures.

Retrograde dynamization is performed by statically locking the nail proximally.

The guided Locking Screw is then placed in the dynamic position of the oblong hole. This allows the nail to move, and the fracture to settle while torsional stability is maintained (Fig. 78).

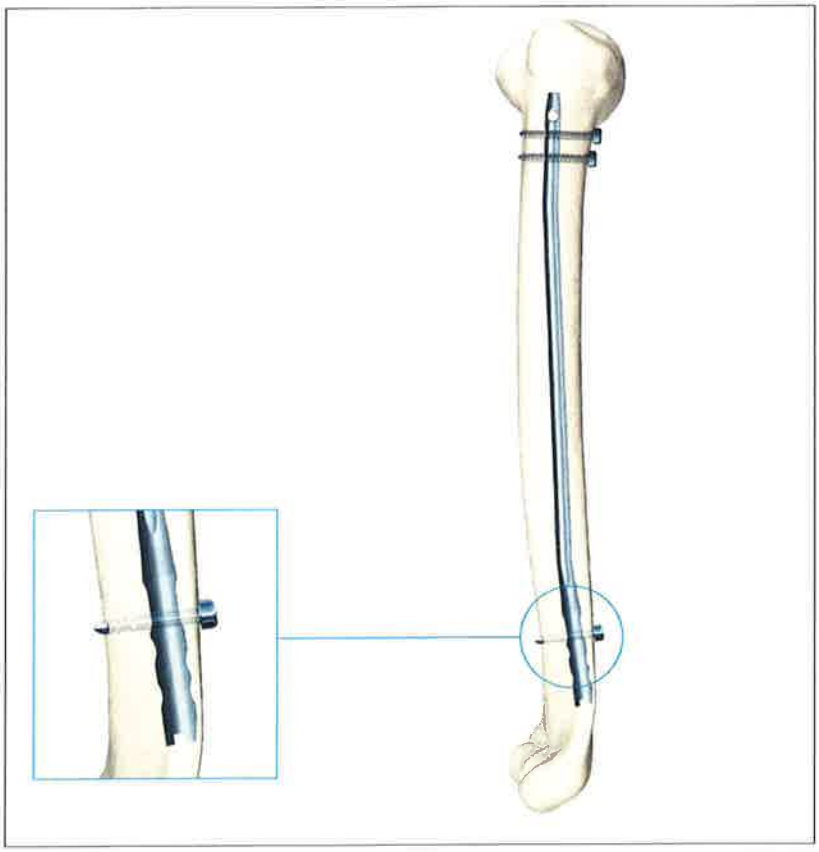


Fig. 78

Apposition/Compression Locking Mode

In transverse or axially stable fracture patterns, active apposition/compression increases fracture stability and enhances fracture healing. The retrograde T2 Humeral Nail provides the option to treat a humerus fracture with active mechanical apposition/compression prior to leaving the operating room.

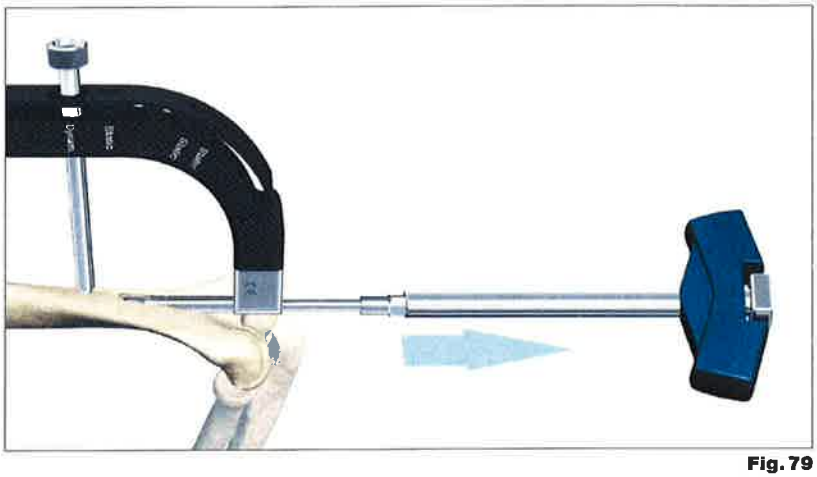


Fig. 79

Note:

Proximal freehand static locking must be performed prior to applying active, controlled apposition/compression to the fracture site.

If active apposition/compression is required, a Partially Threaded Locking Screw (Shaft Screw) is inserted via the Target Device in the dynamic position of the oblong hole. This will allow for a maximum of 6mm of active, controlled apposition/compression. In order to insert the Partially Threaded Locking Screw (Shaft Screw), drill both cortices with the Ø3.5×230mm Drill (1806-3540S). Next, the near cortex ONLY is overdrilled with the Ø4.0×180mm Drill (1806-4000S).

Note:

- **After the opposite cortex is drilled with the Ø3.5×230mm Drill, the correct screw length can be read directly off of the calibrated Drill at the end of the Drill Sleeve.**
- **It may be easier to "insert" the Compression Screw prior to fully seating the nail. Once the nail tip has cleared the fracture site, the Guide Wire (if used) is withdrawn. With the proximal portion of the nail not fully seated and extending out of the bone, the Advanced Compression Screw is inserted.**
- **Care should be taken that the shaft of the Compression Screw does not extend into the area of the oblong hole.**

Operative Technique – Retrograde Technique

After the Partially Threaded Locking Screw (Shaft Screw) is inserted, the Nail Holding Screw is removed, leaving the insertion post intact with the nail (Fig. 79). This will act as a guide for the Compression Screw. The Compression Screw is inserted with the Compression Screwdriver Shaft (1806-0263) assembled on the Teardrop Handle through the insertion post (Fig. 80).

Fig. 80

The Short Tissue Protection Sleeve is removed and the Compression Screw is gently tightened utilizing the two-finger technique (Fig. 81). As the Compression Screw is advanced against the 4.0mm Partially Threaded Locking Screw (Shaft Screw), it draws the proximal fracture segment towards the fracture site, employing active apposition/compression. Image intensification will enable the surgeon to visualize active apposition/compression. Some bending of the transverse Partially Threaded Locking Screw (Shaft Screw) may be seen.

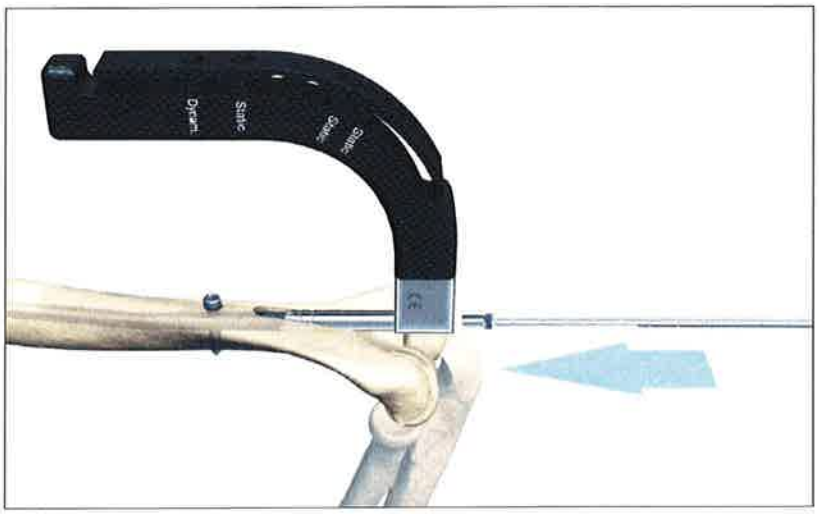


Fig. 81

Note:

- **Apposition/compression must be carried out under X-Ray control. Over-compression may cause the nail or the Partially Threaded Locking Screw (Shaft Screw) to fail.**
- **When compressing the nail, the implant must be inserted a safe distance from the entry point to accommodate for the 6mm of active compression. The three grooves on the insertion post are designed to help attain accurate insertion depth of the implant.**

Advanced Locking Mode

In order to achieve additional fixation and to reduce the load on the Partially Threaded Locking Screw (Shaft Screw), the design of the T2 Humeral Nail provides the opportunity to insert an additional Fully Threaded Locking Screw in the other transverse hole at the driving end of the nail after apposition/compression is utilized.

Prior to guided locking via the Target Device, the Nail Holding Screw must be tightened using the Insertion Wrench.

The Compression Screw is inserted with the Compression Screwdriver Shaft. Fix the Compression Screw on the Compression Screwdriver Shaft. Remove the Nail Holding Screw leaving the Target Device in place (Fig. 82). Advance the Compression Screw through the Target Device until the desired amount of compression is achieved. Visualize depth of insertion with the aid of flouroscopy (Fig. 83).

Note:

As previously described, it may be easier to insert the Compression Screw prior to fully seating the nail.

To reattach the Target Device to the nail, detach the Compression Screw Driver and screw the Nail Holding Screw into its required position. To reattach the Target Device to the nail, detach the Teardrop Handle from the Compression Screwdriver Shaft and screw the Nail Holding Screw over the Compression Screwdriver Shaft into its required position.

To insert the second transverse Fully Threaded Locking Screw, follow the locking procedure for static locking (Fig. 84 and 85).

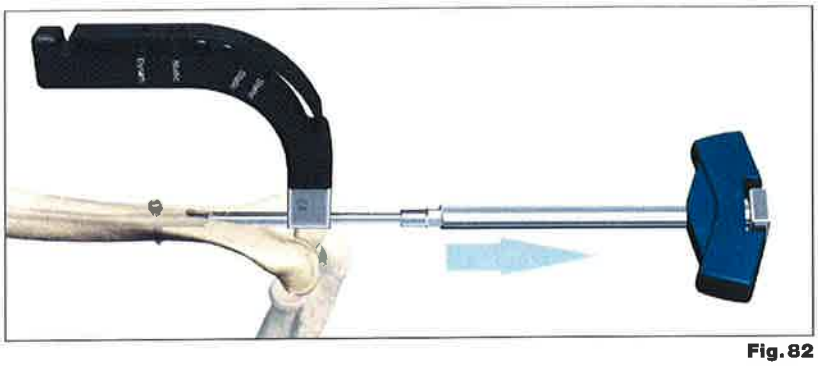


Fig. 82

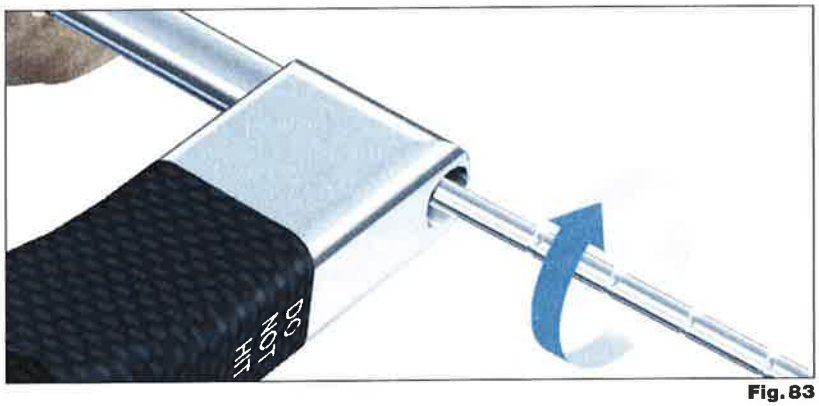


Fig. 83

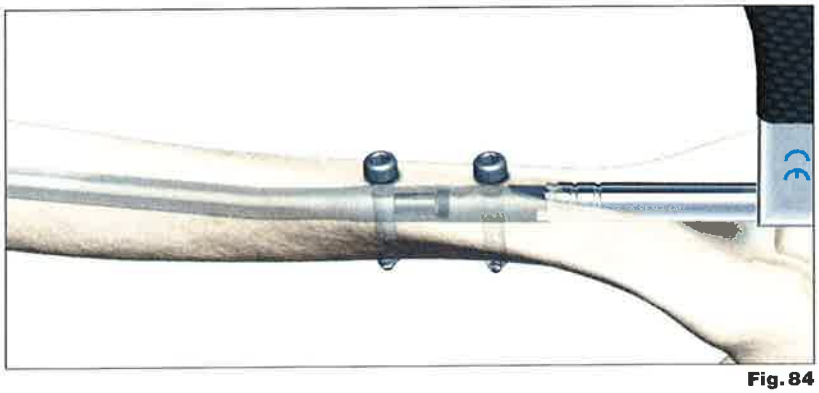


Fig. 84

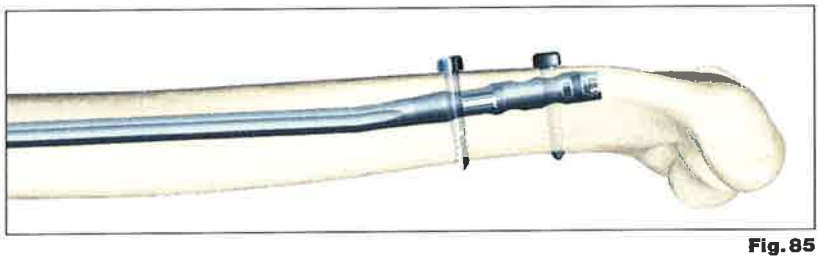


Fig. 85

Nail Removal

Nail removal is an elective procedure. If they were used, the End Cap and Compression Screw are removed with the Short Screwdriver Shaft and the Teardrop Handle. If Advanced Locking Mode was utilized, the most distal screw is extracted first, thus allowing access to the compression screw.

The Universal Rod, Short is inserted into the driving end of the nail before all Locking Screws are removed with the Short Screwdriver Shaft and the Teardrop Handle (Fig. 86).

Note:

Attaching the Universal Rod to the nail first, will reduce the potential for nail migration, then the Locking Screws may be removed safely.

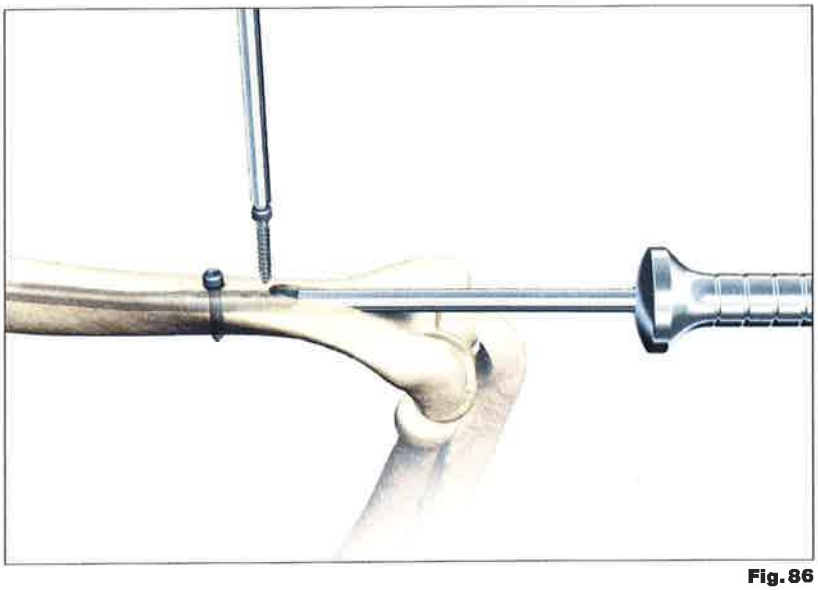


Fig. 86

The Slotted Hammer is used to extract the nail in a controlled manner (Fig. 87).

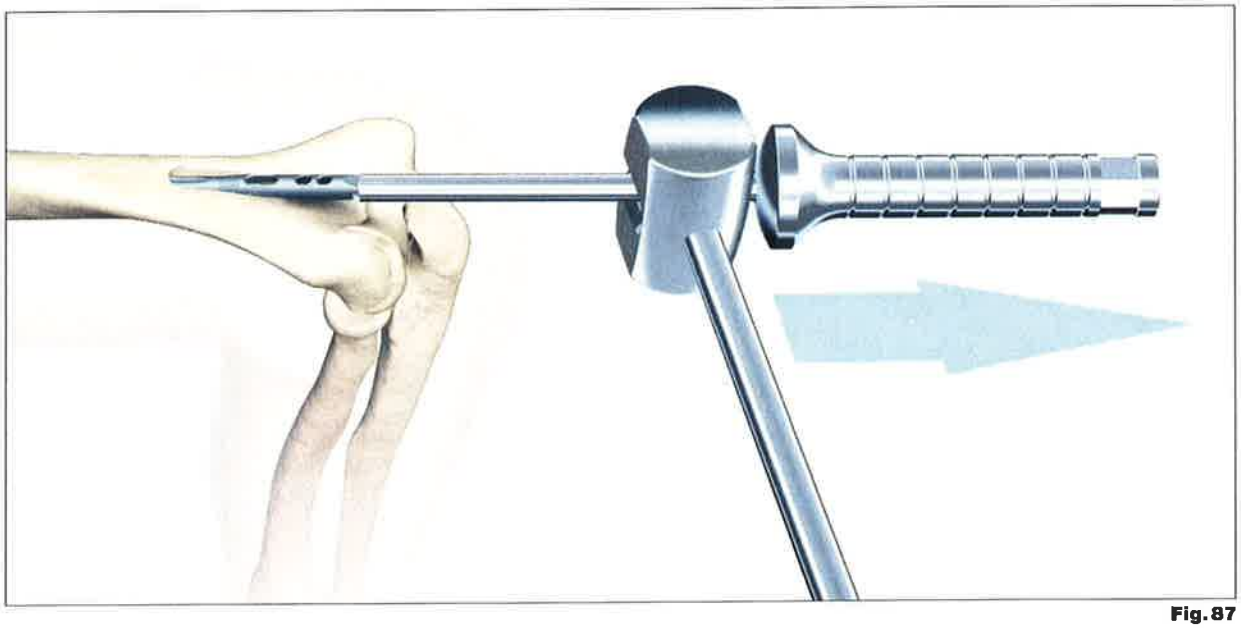


Fig. 87

Ordering Information – Implants

T2 HUMERAL LOCKING NAIL

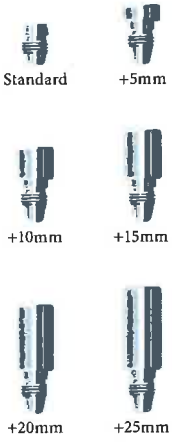
REF	Diameter mm	Length mm
1830-0714S	7.0	140
1830-0716S	7.0	160
1830-0718S	7.0	180
1830-0719S	7.0	190
1830-0720S	7.0	200
1830-0721S	7.0	210
1830-0722S	7.0	220
1830-0723S	7.0	230
1830-0724S	7.0	240
1830-0725S	7.0	250
1830-0726S	7.0	260
1830-0727S	7.0	270
1830-0728S	7.0	280
1830-0729S	7.0	290
1830-0730S	7.0	300
1830-0731S	7.0	310
1830-0732S	7.0	320
1830-0814S	8.0	140
1830-0816S	8.0	160
1830-0818S	8.0	180
1830-0819S	8.0	190
1830-0820S	8.0	200
1830-0821S	8.0	210
1830-0822S	8.0	220
1830-0823S	8.0	230
1830-0824S	8.0	240
1830-0825S	8.0	250
1830-0826S	8.0	260
1830-0827S	8.0	270
1830-0828S	8.0	280
1830-0829S	8.0	290
1830-0830S	8.0	300
1830-0831S	8.0	310
1830-0832S	8.0	320
1830-0914S	9.0	140
1830-0916S	9.0	160
1830-0918S	9.0	180
1830-0919S	9.0	190
1830-0920S	9.0	200
1830-0921S	9.0	210
1830-0922S	9.0	220
1830-0923S	9.0	230
1830-0924S	9.0	240
1830-0925S	9.0	250
1830-0926S	9.0	260
1830-0927S	9.0	270
1830-0928S	9.0	280
1830-0929S	9.0	290
1830-0930S	9.0	300
1830-0931S	9.0	310
1830-0932S	9.0	320

Ordering Information – Implants

4MM FULLY THREADED LOCKING SCREWS+

REF	Diameter mm	Length mm
1896-4020S	4.0	20
1896-4022S	4.0	22
1896-4024S	4.0	24
1896-4025S	4.0	25
1896-4026S	4.0	26
1896-4028S	4.0	28
1896-4030S	4.0	30
1896-4032S	4.0	32
1896-4034S	4.0	34
1896-4035S	4.0	35
1896-4036S	4.0	36
1896-4038S	4.0	38
1896-4040S	4.0	40
1896-4045S	4.0	45
1896-4050S	4.0	50
1896-4055S	4.0	55
1896-4060S	4.0	60

END CAPS



REF	Diameter mm	Length mm
1830-0003S	6.0	±0
1830-0005S	6.0	+5
1830-0010S	6.0	+10
1830-0015S	6.0	+15
1830-0020S	6.0	+20
1830-0025S	6.0	+25

4MM PARTIALLY THREADED LOCKING SCREWS+

(Shaft Screws)

REF	Diameter mm	Length mm
1891-4020S	4.0	20
1891-4022S	4.0	22
1891-4024S	4.0	24
1891-4025S	4.0	25
1891-4026S	4.0	26
1891-4028S	4.0	28
1891-4030S	4.0	30
1891-4032S	4.0	32
1891-4034S	4.0	34
1891-4035S	4.0	35
1891-4036S	4.0	36
1891-4038S	4.0	38
1891-4040S	4.0	40
1891-4045S	4.0	45
1891-4050S	4.0	50
1891-4055S	4.0	55
1891-4060S	4.0	60

WASHERS

REF	Description
1830-0008S	Washer, round
1830-0009S	Washer, square

ADVANCED COMPRESSION SCREW, HUMERUS

REF	Diameter mm
1830-0001S	6.0

Implants in sterile packaging.

Note:
Check with local representative regarding availability of sizes.

+ Outside of the U.S., Locking Screws may be ordered non-sterile without the "S" at the end of the corresponding Catalogue Number.

Ordering Information – Instruments

REF	Description
T2 Basic Short	
702429	Teardrop Handle, AO Coupling
1806-0022	Guide Wire Ruler
1806-0032	Awl Plug
1806-0041	Awl
1806-0113	Universal Rod, Short
1806-0130	Wrench 8mm/10mm
1806-0135	Insertion Wrench, 10mm
1806-0150	Strike Plate
1806-0170	Slotted Hammer
1806-0180	Tissue Protection Sleeve, Short
1806-0203	Screwdriver, Self-Holding, Extra Short (3.5)
1806-0210	Drill Sleeve, Short
1806-0222	Screwdriver Shaft AO
1806-0238	Screwdriver, Self-Holding, Short (3.5)
1806-0310	Trocar, Short
1806-0330	Screw Gauge, Short
1806-0353	Extraction Rod, Conical
1806-0360	Screw Scale, Short
1806-0363	Reduction Rod
1806-0390	Depth Gauge
1806-0410	Rigid Reamer Sleeve Ø10mm
1806-0411	Rigid Reamer Trocar Ø10mm
1806-1095	Guide Wire Handle
1806-1096	Guide Wire Handle Chuck
1806-2020	Crown Drill
1806-9905	T2 Basic Short Instrument Tray

REF	Description
T2 Humerus	
703117	Insertion Site Template
703125	Selfguiding Rigid Reamer
703126	Conical Rigid Reamer
1806-0013	X-Ray Ruler
1806-0050	K-Wire 3×285mm
1806-0051	K-Wire with Washer
1806-0073	Teflon Tube
1806-0143	Target Device
1806-0163	Nail Holding Screw
1806-0263	Screwdriver Saft, Compression (2.5)
1806-3540*	Drill Ø3.5×230mm, AO
1806-3550*	Drill Ø3.5×130mm, AO
1806-4000*	Drill Ø4.0×180mm, AO
1806-9930	T2 Humerus Instrument Tray

Caution:

8mm Nails require 4mm Fully Threaded Screws for locking at the non-driving end.

* Instruments designated "Outside of the U.S." may not be ordered for the U.S. market.

Ordering Information – Instruments

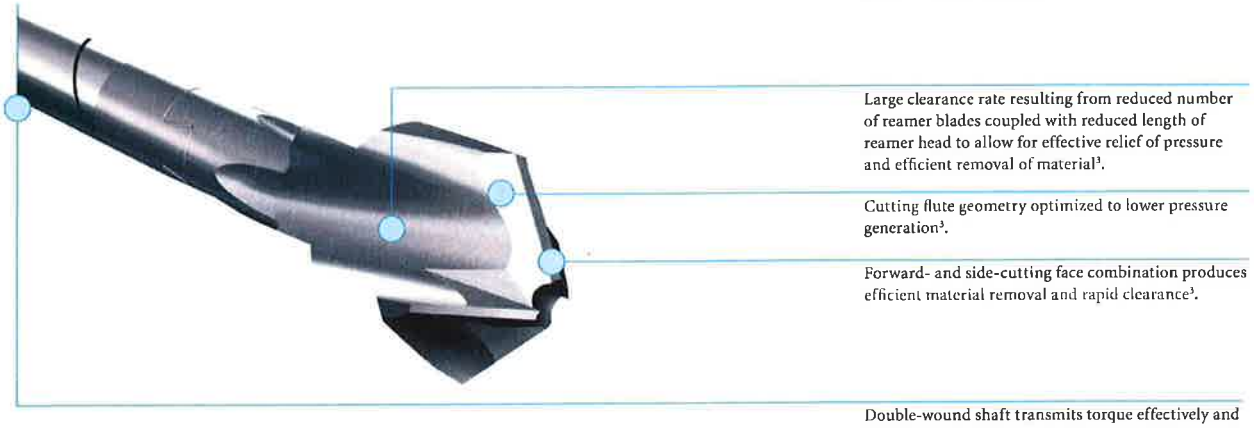
REF	Description
Optional Instruments	
1806-0003	X-Ray Template, Humerus
1806-0045	Awl, Ø10mm Straight
1806-0083	Guide Wire, Ball Tip, Ø2.5×800mm
1806-0093	Guide Wire, Smooth Tip, Ø2.2×800mm
1806-0083S	Guide Wire, Ball Tip, Ø2.5×800mm, Sterile (U.S.)
1806-0093S	Guide Wire, Smooth Tip, Ø2.2×800mm, Sterile (U.S.)
1806-0130	Wrench, 8mm/10mm
1806-0175	Sliding Hammer
1806-3540S	Drill Ø3.5×230mm, AO, sterile (U.S.)
1806-3550	Drill Ø3.5×130mm, AO, (outside of U.S.)
1806-3550S	Drill Ø3.5×130mm, AO, sterile (U.S.)
1806-4000S	Drill Ø 4×180mm, AO, Sterile (U.S.)
1806-9013	Humerus Screw Tray
1806-9972	T2 PHN Drill Rack
1806-9982	Silicon Mat

* Instruments designated "Outside of the U.S." may not be ordered for the U.S. market.

Ordering Information – Instruments

Bixcut

Complete range of modular and fixed-head reamers to match surgeon preference and optimize O.R. efficiency, presented in fully sterilizable cases.



Large clearance rate resulting from reduced number of reamer blades coupled with reduced length of reamer head to allow for effective relief of pressure and efficient removal of material[3].

Cutting flute geometry optimized to lower pressure generation[3].

Forward- and side-cutting face combination produces efficient material removal and rapid clearance[3].

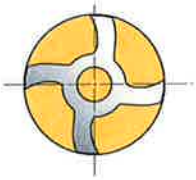
Double-wound shaft transmits torque effectively and with high reliability. Low-friction surface finish aids rapid debris clearance[3].

Smaller, 6 and 8mm shaft diameters are designed to reduce IM pressure.

Typical Standard
Reamer Ø14mm

Clearance area:
32% of cross section

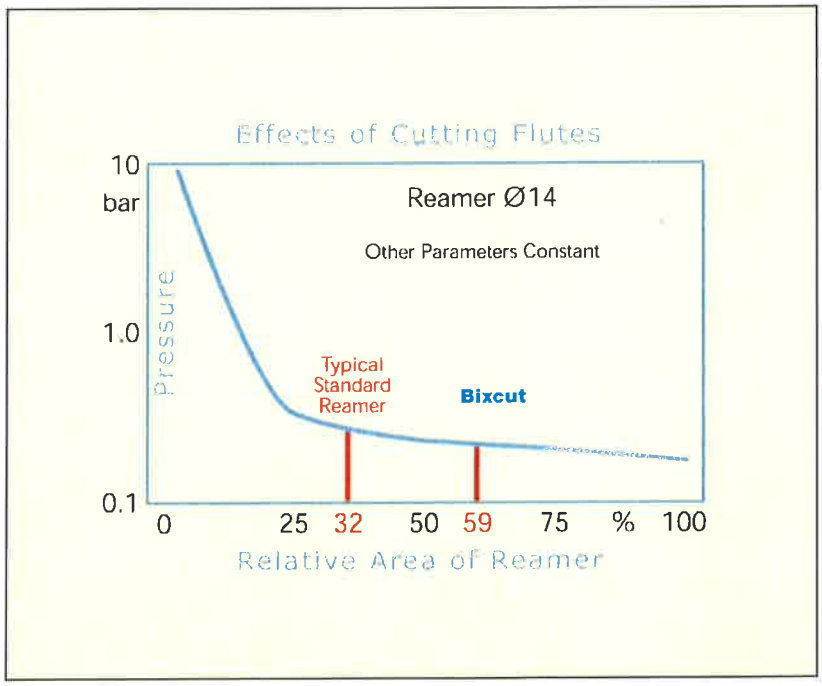
Bixcut
Reamer Ø14mm



Clearance area:
59% of cross section

Studies[1] have demonstrated that the pressures developed within the medullary cavity through the introduction of unreamed IMnails can be far greater than those developed during reaming – but this depends very much upon the design of the reamer.

After a three year development study[2] involving several universities, the factors that determine the pressures and temperatures developed during reaming were clearly established. These factors were applied to the development of advanced reamers that demonstrate significantly better performance than the best of previous designs[3].



1 Jan Paul M. Frolke, et al.;
Intramedullary Pressure in Reamed Femoral Nailing with Two Different Reamer Designs.,
Eur. J. of Trauma, 2001 #5

2 Medhi Moussavi, et al.;
Pressure Changes During Reaming with Different Parameters and Reamer Designs,
Clinical Orthopaedics and Related Research
Number 373, pp. 295-303, 2000

3 Andreas Speitling;
Intramedullary Reamers, commented slides of internal test report, Sep 1999

Ordering Information – Instruments

BIXCUT MODULAR HEAD

REF	Description	Diameter mm
0226-3090	Bixcut Head	9.0
0226-3095	Bixcut Head	9.5
0226-3100	Bixcut Head	10.0
0226-3105	Bixcut Head	10.5
0226-3110	Bixcut Head	11.0
0226-3115	Bixcut Head	11.5
0226-3120	Bixcut Head	12.0
0226-3125	Bixcut Head	12.5
0226-3130	Bixcut Head	13.0
0226-3135	Bixcut Head	13.5
0226-3140	Bixcut Head	14.0
0226-3145	Bixcut Head	14.5
0226-3150	Bixcut Head	15.0
0226-3155	Bixcut Head	15.5
0226-3160	Bixcut Head	16.0
0226-3165	Bixcut Head	16.5
0226-3170	Bixcut Head	17.0
0226-3175	Bixcut Head	17.5
0226-3180	Bixcut Head	18.0
0226-4185	Bixcut Head	18.5
0226-4190	Bixcut Head	19.0
0226-4195	Bixcut Head	19.5
0226-4200	Bixcut Head	20.0
0226-4205	Bixcut Head	20.5
0226-4210	Bixcut Head	21.0
0226-4215	Bixcut Head	21.5
0226-4220	Bixcut Head	22.0
0226-4225	Bixcut Head	22.5
0226-4230	Bixcut Head	23.0
0226-4235	Bixcut Head	23.5
0226-4240	Bixcut Head	24.0
0226-4245	Bixcut Head	24.5
0226-4250	Bixcut Head	25.0
0226-4255	Bixcut Head	25.5
0226-4260	Bixcut Head	26.0
0226-4265	Bixcut Head	26.5
0226-4270	Bixcut Head	27.0
0226-4275	Bixcut Head	27.5
0226-4280	Bixcut Head	28.0

BIXCUT SHAFTS (STERILE)[1,2,3,4]

REF	Description	Length mm
0227-8240S	Mod. Trinkle	284
0227-3000S	Mod. Trinkle	448
0227-8510S	Mod. Trinkle	510
0227-8885S	Mod. Trinkle	885
0226-8240S	AO	284
0226-3000S	AO	448

SHAFT ACCESSORIES

REF	Description
3212-0-210	Grommet (pack of 25)
3212-0-220	Grommet inserter/extractor
0225-6010	Grommet Case

BIXCUT FIXED HEAD – AO FITTING**

REF	Diameter mm	Length mm
0225-5060	6.0*	400
0225-5065	6.5*	400
0225-5070	7.0*	400
0225-6075	7.5	480
0225-6080	8.0	480
0225-6085	8.5	480
0225-6090	9.0	480
0225-6095	9.5	480
0225-6100	10.0	480
0225-6105	10.5	480
0225-6110	11.0	480
0225-8115	11.5	480
0225-8120	12.0	480
0225-8125	12.5	480
0225-8130	13.0	480
0225-8135	13.5	480
0225-8140	14.0	480
0225-8145	14.5	480
0225-8150	15.0	480
0225-8155	15.5	480
0225-8160	16.0	480
0225-8165	16.5	480
0225-8170	17.0	480
0225-8175	17.5	480
0225-8180	18.0	480

OPTIONAL INSTRUMENTS

REF	Description
0227-0060	Hand Reamer 6 mm w/Mod Trinkle connection
0227-0070	Hand Reamer 7 mm w/Mod Trinkle connection
0227-0080	Hand Reamer 8 mm w/Mod Trinkle connection
0227-0090	Hand Reamer 9 mm w/Mod Trinkle connection
1806-6520	Curved Reduction Rod 8.5 mm w/Mod Trinkle connection
1806-6500	T-Handle w/Mod Trinkle connection

BIXCUT TRAYS EMPTY

REF	Description
0225-6000	**Tray, Modular Head (up to size 22.0mm)**
0225-6001	**Tray, Modular Head (up to size 28.0mm)**
0225-8000	**Tray, Fixed Head (up to size 18.0mm)**
0225-6040	Mini Trauma Tray (for modular heads 9-18)
0225-6050	Mini Revision Tray (for modular heads 9-28)

Note:

Bixcut Fixed Head – Modified Trinkle fitting available in same diameters and length as the AO Fitting (REF No: 0227-xxxx)

* Use with 2.2mm × 800mm Smooth Tip and 2.5mm × 800mm Ball Tip Guide Wires only.

** Use with Stryker Power Equipment.

1. Non-Sterile shafts supplied without grommet. Use new grommet for each surgery. See Shaft Accessories.
2. Sterile shafts supplied with grommet pre-assembled.
3. For Non-Sterile leave "S" off the REF Number when ordering (510 and 885mm available only sterile Modified Trinkle Fitting).
4. Non-Sterile, AO Fitting Shafts in 510 and 885mm are available as build to order items:

- CM810921 AO Fitting Shaft, length 510mm
- CM810923 AO Fitting Shaft, length 885mm.

Notes

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Prof.-Küntscher-Straße 1-5
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