ARZZT®
ALWAYS ONE STEP AHEAD
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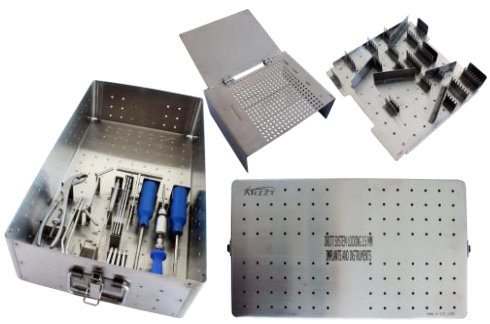
Small Fragments
3.5 LOCKING PLATE SYSTEM

Surgical Technique

Locking and Cortex Screws
Limited Contact Profile
Manufactured in Titanium Ti6Al4V-ELI



Approved by
FDA U.S. FOOD & DRUG ADMINISTRATION

3.5 Locking Plate System
Small Fragments
Code 08070001

Contents

Product Information

IMPORTANT:

- This device has not been evaluated for safety and compatibility in the MR environment
- This device has not been tasted for heating or migration in the MR environment

Introduction

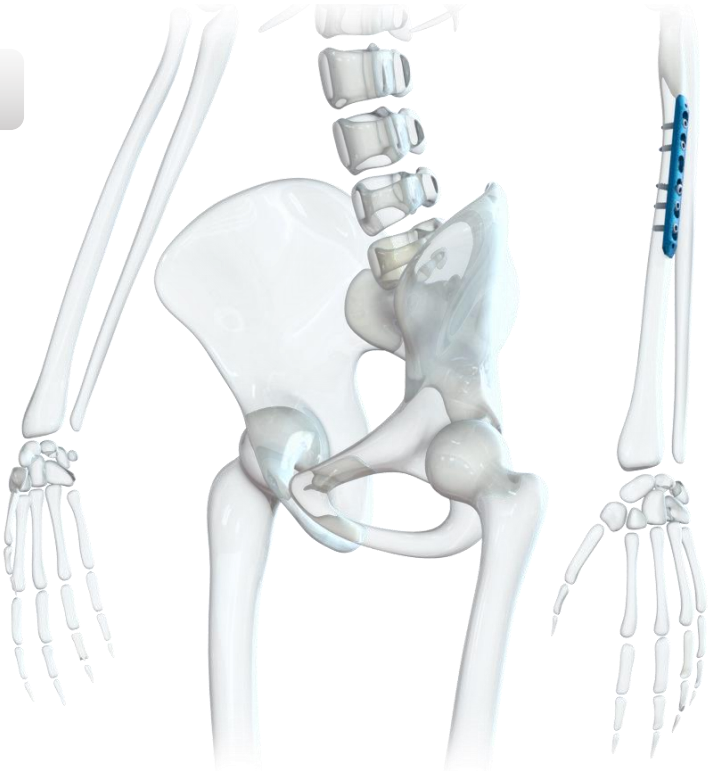
Manufactured in titanium **Ti6Al4V-ELI**

Forearm Locking Plate

- Plate with 5 to 12 combination locking/compression holes
- Holes in both ends for 2.0 mm Kirschner wires
- "Tapered end" for submuscular plate insertion, improving tissue viability.
- The plate holes accept 2.7mm and 3.5 mm ocking screws in the threaded portion and 3.5 mm cortex screws and 4.0 mm cancellous bone screws in the compression portion.

Indications

Extra-articular and simple intra-articular medial radius and ulna bone fractures diaphyseal fractures of the radius and ulna.



Introduction

Manufactured in titanium **Ti6Al4V-ELI**

Proximal Humerus Locking Plate

- Pseudarthroses in the proximal humerus
- Osteotomies in the proximal humerus
- Anatomically Shaped
- 8 proximal screw holes for 3.5mm locking screws
- 1 proximal screw hole for 3.5 cortex or 4.0 cancellous screw
- 3.5 Cortex, 3.5 Locking or 4.0 Cancellous Screws for distal holes
- 13 Proximal holes for 2.0 mm Kirschner wires

Indications

Dislocated two-, three-, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone.

Introduction

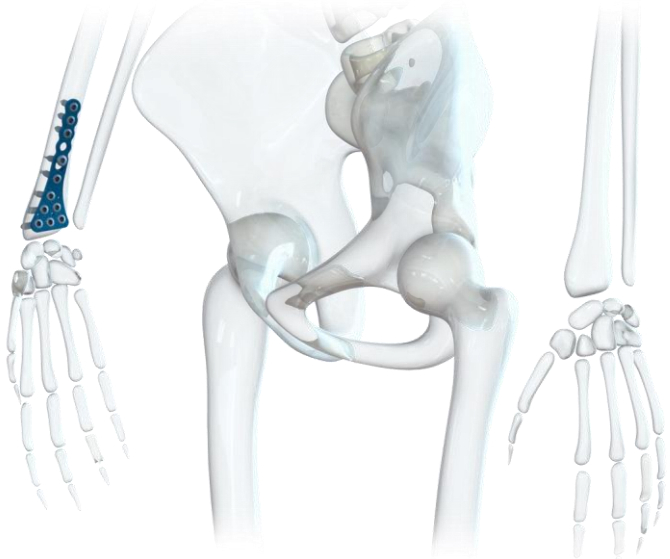
Manufactured in titanium **Ti6Al4V-ELI**

Wrist Surgery Locking Plate

- Available for left and right distal radius
- Shaft with 4 to 6 locking holes with one dynamic orifice for 3.5 mm cortex, or 4.0 mm cancellous bone screws
- 5 Distal locking holes accept 2.7 mm locking, 3.5 mm locking
- 3 distal holes for 1.6 mm Kirschner wires
- The shaft holes accept 2.7mm and 3.5 mm locking screws in the threaded portion
- 3.5 mm cortex screws and 4.0 mm cancellous bone screws in the compression portion

Indications

Temporary fixation, correction or stabilization in the radius anatomical region. It is indicated for the fixation of intra- and extra-articular fractures and osteotomies of the distal radius.



Introduction

Manufactured in titanium **Ti6Al4V-ELI**

Distal Tibia Locking Plate

- Limited contact profile. Design reduces plate to-bone contact, limiting vascular trauma
- Available for left and right tibias
- Shaft with 6 to 12 combination locking/compression holes
- 8 Distal locking holes accept 3.5 mm locking
- Shaft 3.5 locking, 3.5 mm cortex, or 4.0 mm cancellous bone screws in the compression portion
- Proximal and distal holes for 2.0 mm Kirschner wires
- Distal tab for optional medial malleolus screw accepts 3.5 mm locking, 2.7 mm locking. The tab can bend, contour or cut if required.
- Anatomically contoured; plate is twisted and bent to fit distal Tibia

Indications

- Extra-articular and simple intra-articular distal tibial fractures
- Distal tibial fractures, percutaneous or reducible by limited arthrotomy
- Distal tibial fracture extending into the diaphyseal area

3.5 Locking Plate System

Introduction

Manufactured in titanium **Ti6Al4V-ELI**

1/3 Semi tubular Locking Plate

- Plate with 5 to 12 combination locking/compression holes
- In both ends of the plate holes for 1.6 mm Kirschner wires.
- The plate holes accept 2.7mm and 3.5 mm locking screws in the threaded portion and 3.5 mm cortex screws and 4.0 mm cancellous bone screws in the compression portion

Indications

Extra-articular and simple intra-articular distal fibula bone fractures: Diaphyseal fractures of the fibula, metaphyseal fractures of the fibula.

General Surgical Technique

Screw Insertion

All plates holes accept 2.7mm and 3.5mm locking screws in the threaded portion and 3.5 mm cortex screws in the compression portion. 4.0 cancellous screws may be used for fixation of poor quality or metaphyseal bone.

If a combination of locking and cortex screws is planned, a cortex screw should be used first to pull the plate to the bone.

If a locking screw is used first, care should be taken to ensure that the plate is held securely to the bone to keep the plate from rotating off the bone as the screw is locked into the plate. Plates have holes for 1.6 mm Kirschner wires to secure them.

3.5 Cortex Screw

2.7 mm and 3.5 mm Locking Screw

4.0 mm Cancellous Screw

IMPORTANT:

A power drilling machine or drill bit handle is not provided with the instruments. Surgeon may use preferred instrument.

General Surgical Technique

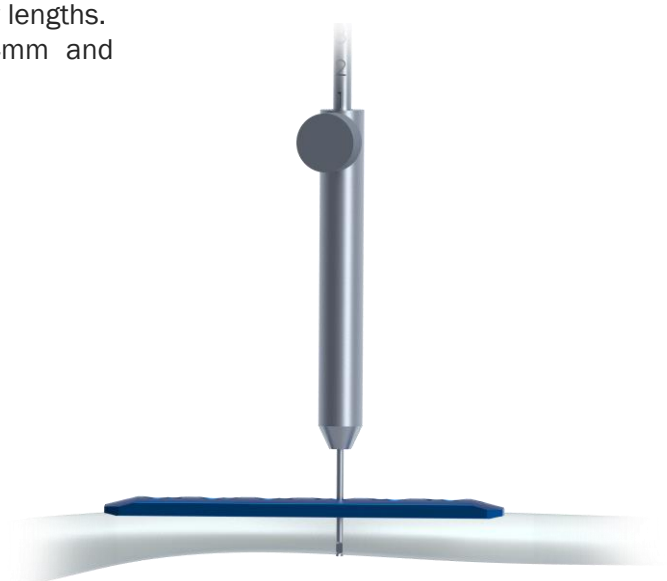
1
Insert cortex or cancellous screws

Instruments:

07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide

Use the 2.7/3.2 Double Drill Guide for an eccentric (compression) or neutral (buttress) insertion of cortex screws.

Use the 2.7 mm drill bit with depth mark for 3.5mm cortex screws and 3.2mm drill bit with depth mark for 4.5mm cancellous screws to drill to the desired depth.
Use the depth gauge to measure for screw lengths.
Use a StarDrive screwdriver for all 2.4mm and 2.7mm cortex screws.



General Surgical Technique

2
Insert locking screws

Instruments:

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07022106	3.5 StarDrive Screwdriver with torque
07080113	Short Depth Gauge
07032108	2.7mm Drill Guide
70321033	3.5mm Drill Guide

Screw the threaded 2.7mm drill guide for 2.7mm screws and the 3.5mm drill guide for 3.5mm screws into a locking hole until it is fully seated.

Use the 2.0mm drill bit with depth mark for 2.7mm screws and a 2.7mm drill bit with depth mark for 3.5mm screws to drill to the desired depth.

Determine screw length

Remove the drill guide.
Use the depth gauge to measure the screw length

Insert screw

Insert locking screws manually with a T8 StarDrive screwdriver.
Carefully tighten the locking screw. Excessive force is not necessary to lock the screw to the plate.

General Surgical Technique

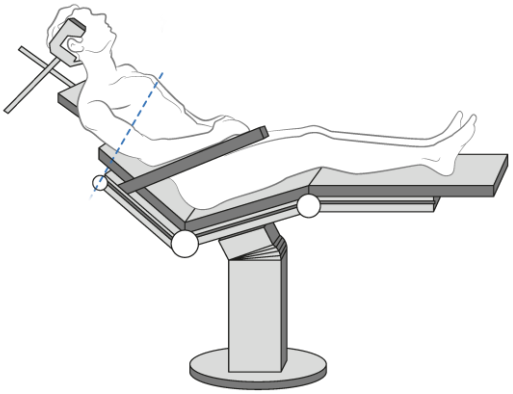
Position Patient

Complete de preoperative radiographic assessment and prepare the preoperative plan. Determine plate lenght and instruments to be used.

The following positions are recommended for each plate on a radiolucent operating table.

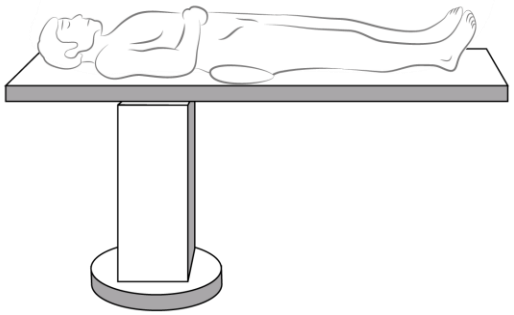
Viewing the bone under fluoroscopy in both the lateral and AP views is necessary.

Make an incision according to the fracture site and pattern



FOWLER´S POSITION

Proximal Humerus Locking Plate

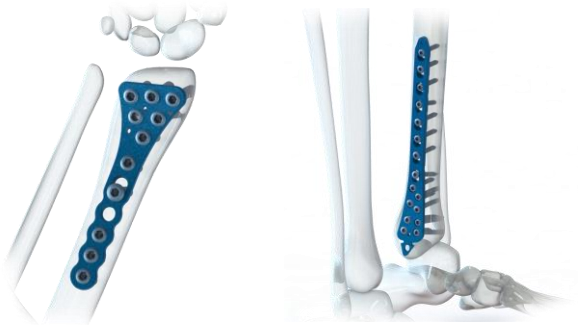


SUPINE POSITION

With Extended Arm on Operating Side Table
Forearm Locking Plate
Wrist Surgery Locking Plate

With Leg on Operating Table
Distal Tibia Locking Plate
1/3 Semi-Tubular Locking Plate

Wrist Surgery Locking Plate
Distal Tibia Locking Plate



Reduce fracture and position plate

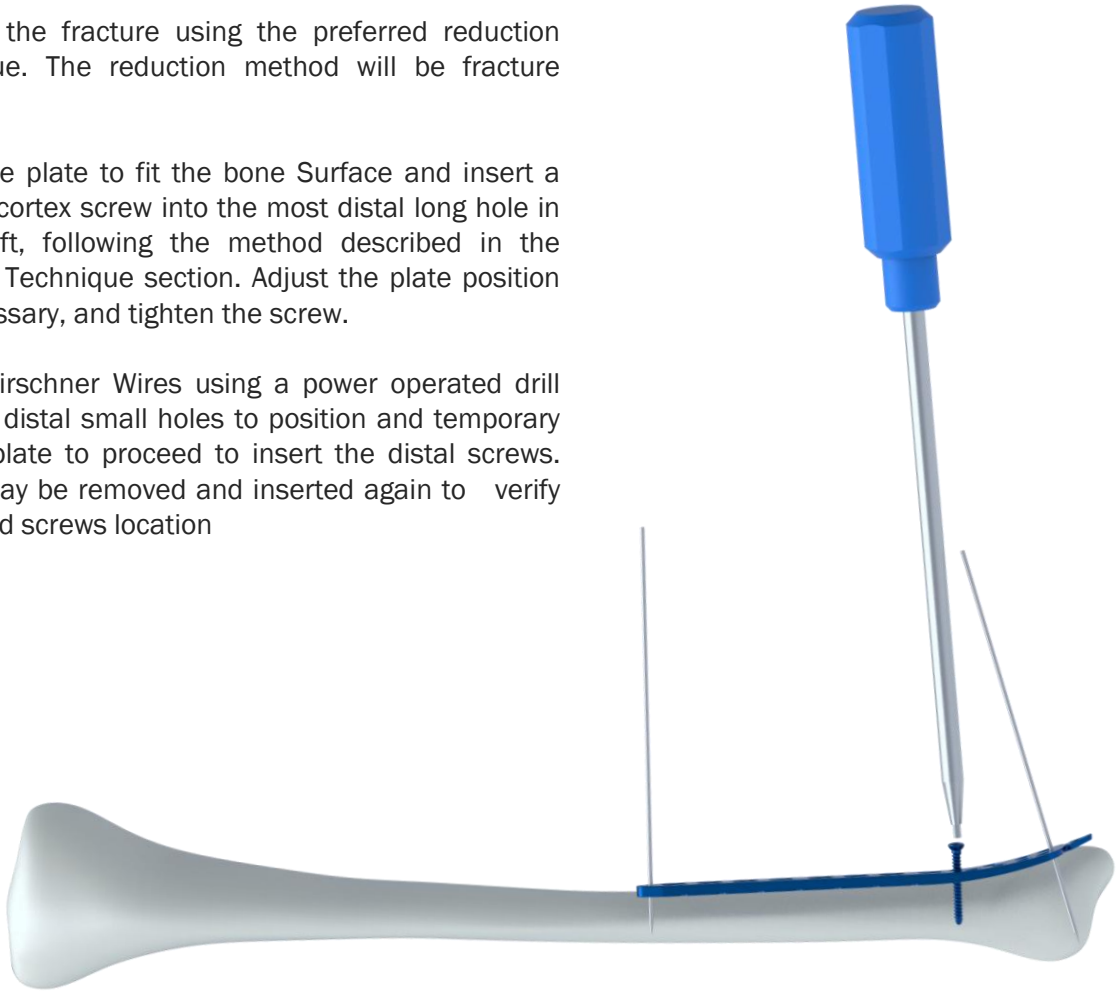
nstruments

07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide

Reduce the fracture using the preferred reduction technique. The reduction method will be fracture specific.

Apply the plate to fit the bone Surface and insert a 3.5mm cortex screw into the most distal long hole in the shaft, following the method described in the General Technique section. Adjust the plate position as necessary, and tighten the screw.

Insert Kirschner Wires using a power operated drill into the distal small holes to position and temporary fix the plate to proceed to insert the distal screws. Wires may be removed and inserted again to verify plate and screws location



Stardrive Self-tapping Locking Screw

- Ø 2.7 mm
- Ø 3.5 mm

Self-tapping Cortex Screw

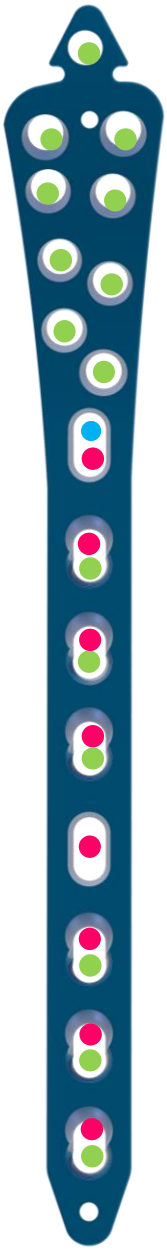
- Ø 3.5 mm

Cancellous Screw

- Ø 4.0 mm

Wrist Surgery Locking Plate

Distal Tibia Locking Plate



Insert Distal Screws

Instruments

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07022106	3.5 StarDrive Screwdriver with torque
07080113	Short Depth Gauge
07032108	2.7mm Drill Guide
07032103	3.5mm Drill Guide

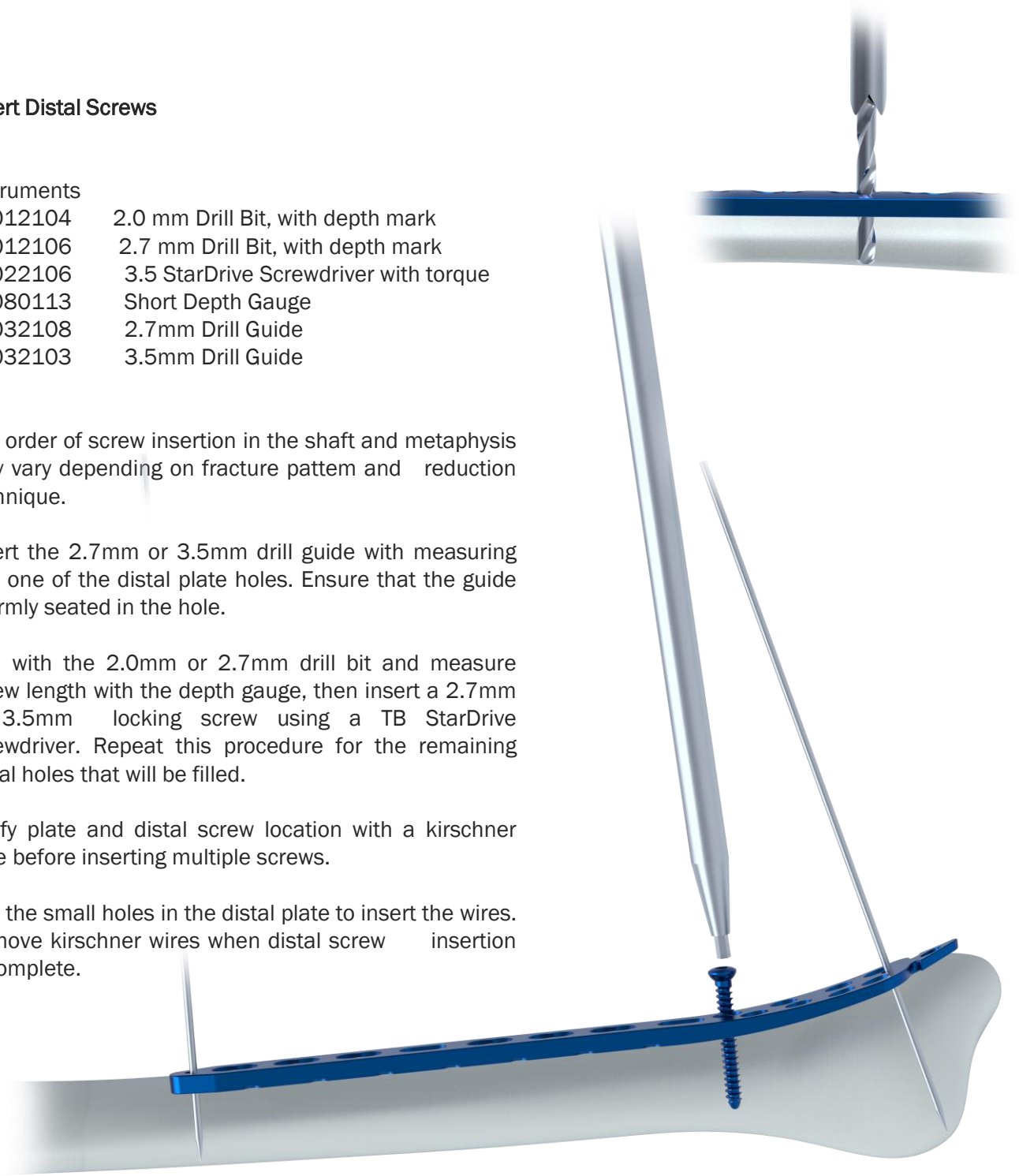
The order of screw insertion in the shaft and metaphysis may vary depending on fracture pattem and reduction technique.

Insert the 2.7mm or 3.5mm drill guide with measuring into one of the distal plate holes. Ensure that the guide is firmly seated in the hole.

Drill with the 2.0mm or 2.7mm drill bit and measure screw length with the depth gauge, then insert a 2.7mm or 3.5mm locking screw using a TB StarDrive screwdriver. Repeat this procedure for the remaining distal holes that will be filled.

Verify plate and distal screw location with a kirschner Wire before inserting multiple screws.

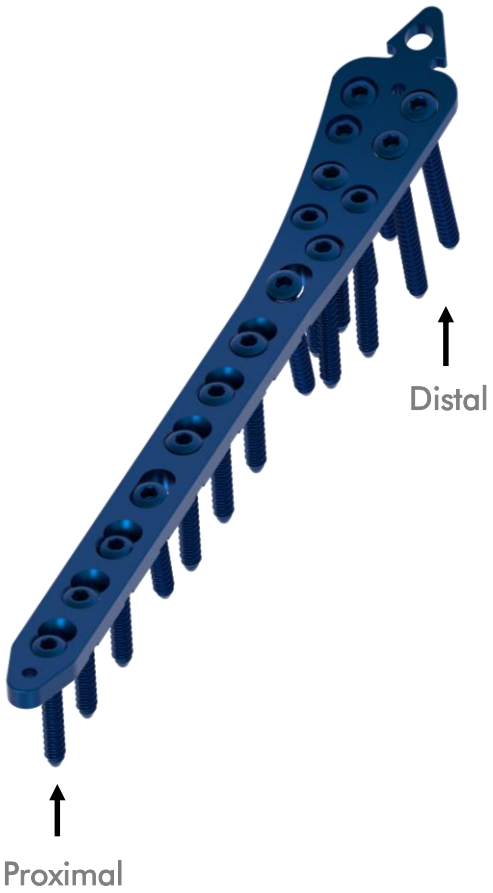
Use the small holes in the distal plate to insert the wires. Remove kirschner wires when distal screw insertion is complete.



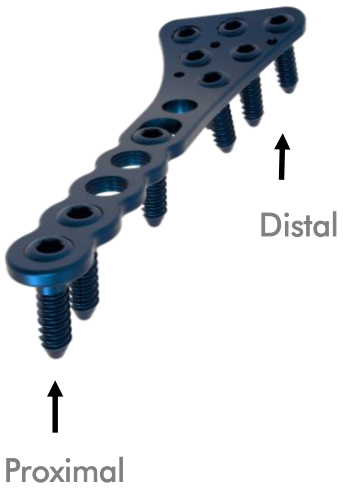
Insert Distal Screws

Instruments

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07022106	3.5 StarDrive Screwdriver with torque
07032108	2.7mm Drill Guide
07032103	3.5mm Drill Guide
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide



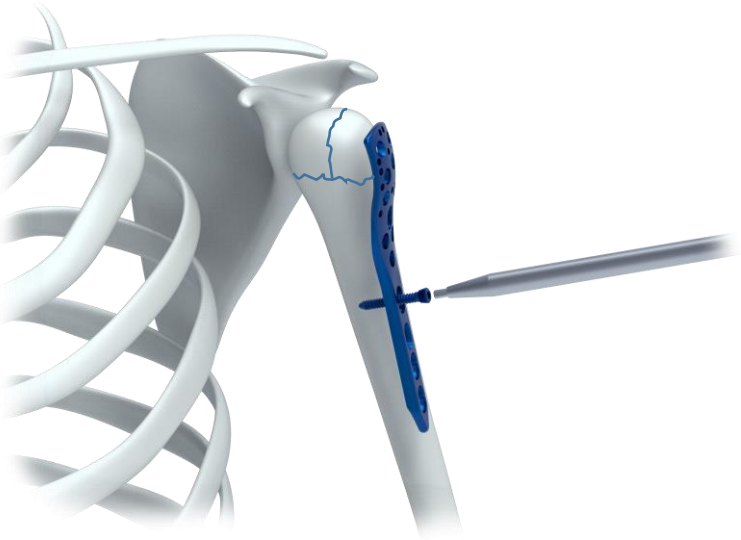
Determine where the 2.7mm or 3.5mm locking or 3.5mm cortex or 4.0mm cancellous screws will be used in the shaft of the plate. Following the steps described in the General Technique section, insert these screws, beginning with the most distal screw.



Reduce fracture and position plate

Instruments

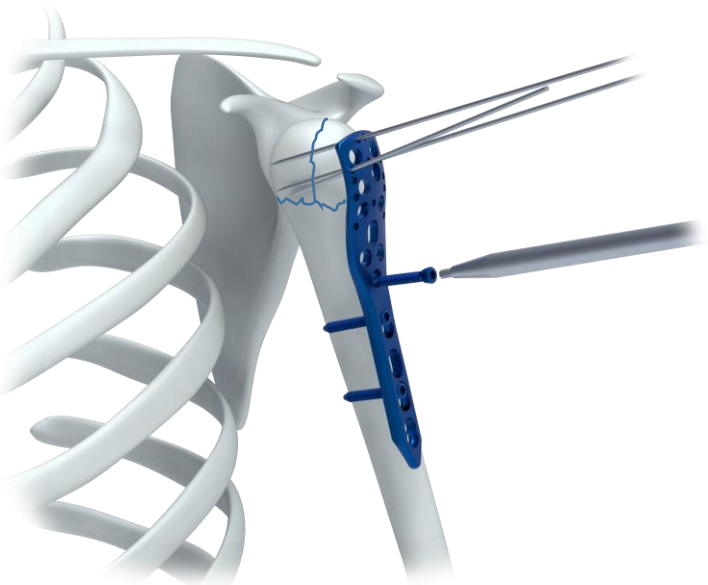
07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide



Reduce the fracture using the preferred reduction technique. The reduction method will be fracture specific.

Apply the plate to fit the bone Surface and insert a 3.5mm cortex screw into the most proximal long hole in the shaft, following the method described in the General Technique section. Adjust the plate position as necessary, and tighten the screw.

Insert Kirschner Wires using a power operated drill into the proximal small hole to position and temporary fix the plate to proceed to insert the distal screws. Wires may be removed and inserted again to verify plate and screws location.



Proximal Humerus
Locking Plate

Stardrive Self-tapping Locking Screw

- Ø 2.7 mm
- Ø 3.5 mm

Self-tapping Cortex Screw

- Ø 3.5 mm

Cancellous Screw

- Ø 4.0 mm

Proximal Humerus Locking Plate

Insert Distal Screws

Instruments

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07022106	3.5 StarDrive Screwdriver with torque
07080113	Short Depth Gauge
07032108	2.7mm Drill Guide
07032103	3.5mm Drill Guide

The order of screw insertion in the shaft and metaphysis may vary depending on fracture pattem and reduction technique.

Insert the 2.7mm or 3.5mm drill guide with measuring into one of the proximal plate holes. Ensure that the guide is firmly seated in the hole.

Drill with the 2.0mm or 2.7mm drill bit and measure screw length with the depth gauge, then insert a 2.7mm or 3.5mm locking screw using a TB StarDrive screwdriver. Repeat this procedure for the remaining proximal holes that will be filled.

Verify plate and proximal screw location with a kirschner Wire before inserting multiple screws.

Use the small hole in the proximal plate to insert the wire. Remove kirschner wire when proximal screw insertion is complete.

Insert Distal Screws

Instruments

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07022106	3.5 StarDrive Screwdriver with torque
07032108	2.7mm Drill Guide
07032103	3.5mm Drill Guide
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide

Determine where the 2.7mm or 3.5mm locking or 3.5mm cortex or 4.0mm cancellous screws will be used in the shaft of the plate. Following the steps described in the General Technique section, insert these screws, beginning with the most distal screw.

Forearm Locking Plate

1/3 Semi-Tubular Locking Plate

Reduce fracture and position plate

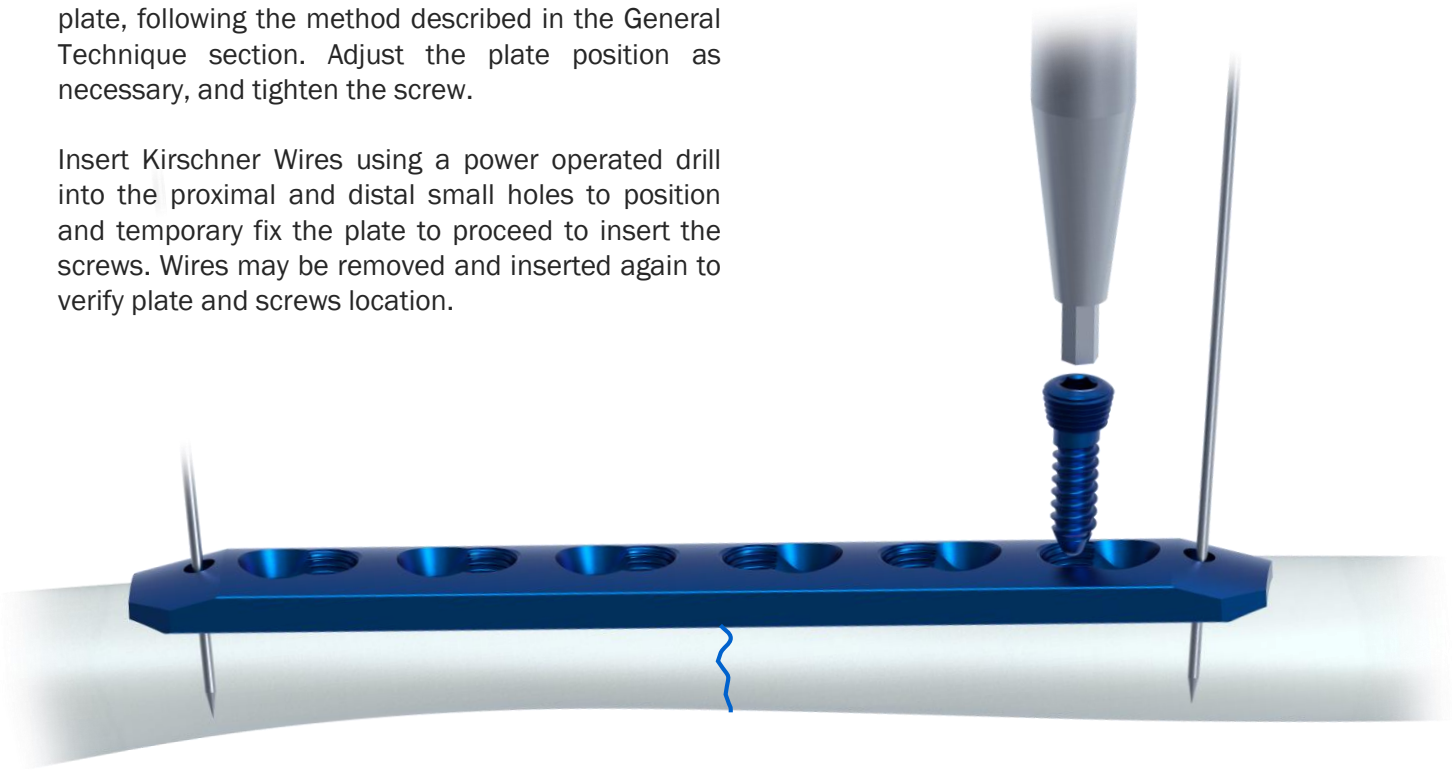
Instruments

07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide

Reduce the fracture using the preferred reduction technique. The reduction method will be fracture specific.

Apply the plate to fit the bone Surface and insert a 3.5mm cortex screw into a center long hole in the plate, following the method described in the General Technique section. Adjust the plate position as necessary, and tighten the screw.

Insert Kirschner Wires using a power operated drill into the proximal and distal small holes to position and temporary fix the plate to proceed to insert the screws. Wires may be removed and inserted again to verify plate and screws location.



Stardrive Self-tapping Locking Screw

- Ø 2.7 mm
- Ø 3.5 mm

Self-tapping Cortex Screw

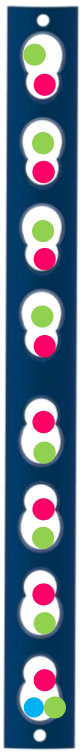
- Ø 3.5 mm

Cancellous Screw

- Ø 4.0 mm

Forearm Locking Plate

1/3 Semi-Tubular Locking Plate



Insert Screws

Instruments

07012104	2.0 mm Drill Bit, with depth mark
07012106	2.7 mm Drill Bit, with depth mark
07012107	3.2 mm Drill Bit, with depth mark
07023103	3.5 Solid Screwdriver
07022106	3.5 StarDrive Screwdriver with torque
07032108	2.7mm Drill Guide
07032103	3.5mm Drill Guide
07080113	Short Depth Gauge
07031104	2.7/3.2 Double Drill Guide

The order of screw insertion in the shaft and metaphysis may vary depending on fracture pattem and reduction technique.

Determine how many locking and cortex screws will be used and the locations.

For locking screws, insert the 2.7mm or 3.5mm drill guide into one of plate holes. Ensure that the guide is firmly seated in the hole.

Drill with the 2.0mm or 2.7mm drill bit and measure screw length with the depth gauge, then insert a 2.7mm or a 3.5mm locking screw using a TB StarDrive screwdriver. Repeat this procedure for the remaining holes that will be filled with locking screws

For cortex screws, follow the steps described in the General Technique section

Verify plate and proximal screw location with a kirschner Wire before inserting multiple screws.

Use the small hole in the proximal plate to insert the wire. Remove kirschner wire when proximal screw insertion is complete.

1/3 Semi-Tubular Locking Plate

Forearm Locking Plate

Confirm proper joint reconstruction

Confirm proper joint reconstruction, screw placement, and screw length, using multiple radiographic views.

Close incision

Use the appropiate method for surgical closure of the incision.

Postoperative treatment

Postoperative treatment with locking compression plates does not differ from conventional internal fixation procedures.

Implant Removal

To remove locking screws, unlock all screws from the plate and then remove screws completely from the bone. This prevents rotation of the plate when removing the last locking screw.

Implants

Forearm Locking Plate

Code	Holes	Width
03023201	5	74 mm
03023202	6	86 mm
03023203	7	98 mm
03023204	8	110 mm
03023205	9	122 mm
03023206	10	134 mm
03023207	12	158 mm

Proximal Humerus Locking Plate

Code	Holes	Width
03121201	3	98.3 mm
03121202	4	110.3 mm
03121204	6	134.3 mm
03121206	8	158.3 mm
03121208	10	182.3 mm

Wrist Surgery Locking Plate

Code	Side	Holes	Width
03131201	Right	4	54.26 mm
03131202	Right	5	61.01 mm
03131203	Right	6	67.76 mm
03131204	Left	4	54.26 mm
03131205	Left	5	61.01 mm
03131206	Left	6	67.76 mm

Distal Tibia Locking Plate

Code	Side	Holes	Width
03141101	Right	6	138.73 mm
03141103	Right	8	164.73 mm
03141105	Right	10	191.75 mm
03141107	Right	12	214.74 mm
03141109	Right	14	244.75 mm
03141110	Left	6	138.73 mm
03141112	Left	8	164.73 mm
03141114	Left	10	191.75 mm
03141116	Left	12	214.74 mm
03141118	Left	14	244.75 mm

Implants

1/3 Semi Tubular Locking Plate

Code	Holes	Width
03072201	5	*62 mm*
03072202	6	73 mm
03072203	7	84 mm
03072204	8	95 mm
03072205	9	106 mm
03072206	10	117 mm
03072208	12	139 mm

Stardrive Self-tapping Locking Screw

Ø 2.7 mm		Ø 3.5 mm	
Code	Length	Code	Length
02094203	14 mm	02091201	10 mm
02094204	16 mm	02091202	12 mm
02094205	18 mm	02091203	14 mm
02094206	20 mm	02091204	16 mm
02094207	22 mm	02091205	18 mm
02094208	24 mm	02091206	20 mm
02094217	45 mm	02091207	22 mm
		02091208	24 mm
		02091209	26 mm
		02091210	28 mm
		02091211	30 mm
		02091212	32 mm
		02091213	34 mm
		02091214	36 mm
		02091215	38 mm
		02091216	40 mm
		02091217	45 mm
		02091218	50 mm

Self-tapping Cortex Screw

Ø 3.5 mm			
Code	Length	Code	Length
02051201	10 mm	02051210	28 mm
02051202	12 mm	02051211	30 mm
02051203	14 mm	02051212	32 mm
02051204	16 mm	02051213	34 mm
02051205	18 mm	02051214	36 mm
02051206	20 mm	02051215	38 mm
02051207	22 mm	02051216	40 mm
02051208	24 mm	02051217	45 mm
02051209	26 mm	02051218	50 mm

Cancellous Screw

Ø 4.0 mm			
Code	Length	Code	Length
02061201	10 mm	02061210	28 mm
02061202	12 mm	02061211	30 mm
02061203	14 mm	02061212	32 mm
02061204	16 mm	02061213	34 mm
02061205	18 mm	02061214	36 mm
02061206	20 mm	02061215	38 mm
02061207	22 mm	02061216	40 mm
02061208	24 mm	02061217	45 mm
02061209	26 mm	02061218	50 mm

Set of Instruments

Drill Bit with depth mark

2.0 mm Code 07012104
2.7 mm Code 07012106
3.2 mm Code 07012107

Dobule Drill Guide

2.7/3.2 mm Code 07031104

StarDrive Screwriver with torque

3.5mm Code 07022106

Depth Gauge

Short Code 07080113

Kirschner Wire

1.6 mm Code 01013103

Set of Instruments

Solid Screwdriver

3.5 mm Code 07023103

Hoffman Retractor

12 mm Code 07070101

Drill Guide

2.7 mm Code 07032108
3.5 mm Code 07032103

Screw Clamp

Code 07050108

Verbrugee Clamp

Small Code 07050109

Set of Instruments

Straight Osteotome

1/4 Code 07080121

T Tap with Drill

3.5mm Code 07043102

Sterelization Box

Code 08012147

ARZZT®

ALWAYS ONE STEP AHEAD

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Approved by

FDA U.S. FOOD & DRUG ADMINISTRATION

3.5 Locking Plate System
Small Fragments

Code 08070001