

6.5 MM AND 4.0 MM CANNULATED SCREWS



S U R G I C A L T E C H N I Q U E

6.5 MM AND 4.0 MM CANNULATED SCREWS

by

David Seligson, M.D.
Professor
Department of Orthopaedics
University of Louisville
Louisville, Kentucky
Chief of Fracture Service

T A B L E O F C O N T E N T S

6.5 MM CANNULATED SCREW

Design Features.....	3
Surgical Technique — Open.....	4
Surgical Technique — Percutaneous.....	6
Screw Removal	8

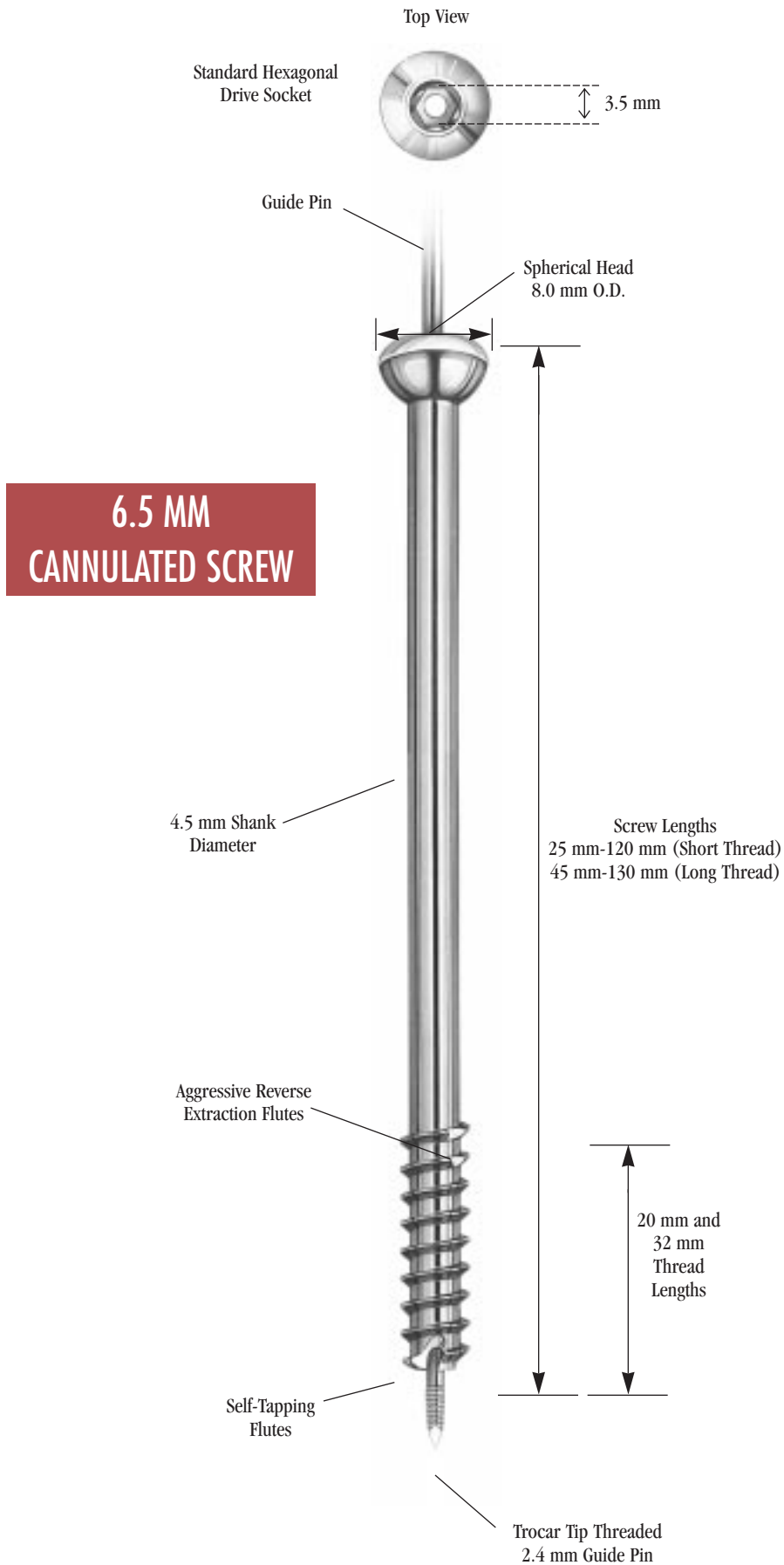
4.0 MM CANNULATED SCREW

Design Features.....	9
Surgical Technique.....	10
Technique Options.....	12
Screw Removal	14

CATALOG INFORMATION	15
---------------------------	----

Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

The following statement is required by the U.S. FDA.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

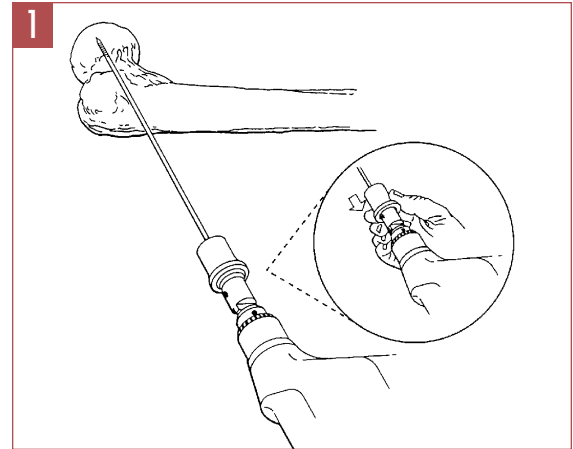


6.5 MM OPEN SURGICAL TECHNIQUE

1 INSERT GUIDE PIN –

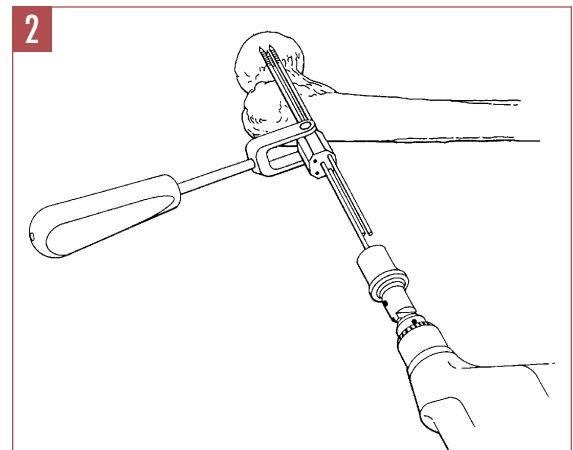
The 2.4 mm Guide Pin (41-0236) slips into the 6.5 mm Quick-Chuck Adapter (7111-0306)* by pulling back the cap on the adapter. The guide pin is then inserted quickly and easily into bone. (Optional: the 4.7 mm Twist Drill (21-0446) is provided to notch the cortex before inserting the pin. This helps prevent the guide pin from deflecting off the bone.) When removing the instruments from the adapter, it may be necessary to first rotate the power source 90° counterclockwise.

**The 6.5 mm Quick-Chuck Adapter is compatible with Amsco Hall, Jacobs, and Stryker power equipment.*



2 INSERT PARALLEL PINS –

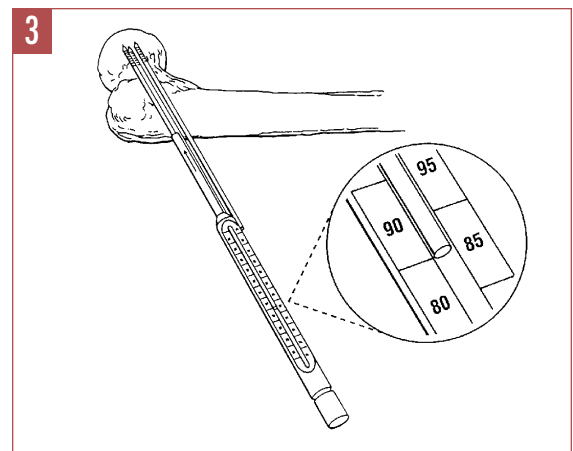
Once the 6.5 mm Cannulated Screw Parallel Pin Guide (7111-0305) is placed over the initial guide pin, the pin block is stationary, and the instrument can be rotated for the placement of multiple parallel pins. The spacing of the pin holes in the instrument prevents the screw heads from overlapping in any configuration.



3 MEASURE –

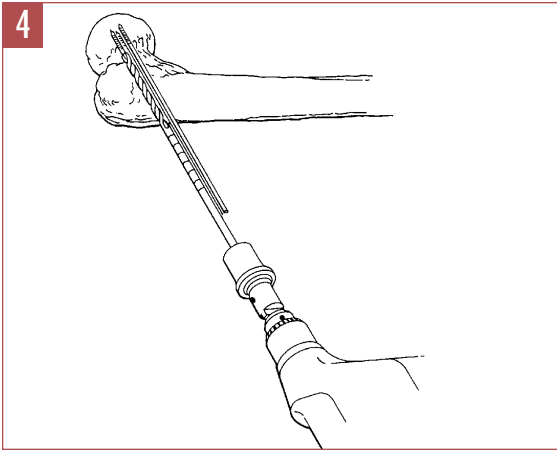
The 6.5 mm Cannulated Screw Direct Measuring Gauge (7111-0308) is placed over the guide pin and directly against bone for accurate measurement. Screw length measurement is read from the back of the guide pin.

Note: The Direct Measuring Gauge is calibrated to display the actual length of guide pin within the bone. Overall screw lengths of the 6.5 mm Cannulated Screw are measured from the top of the head to the tip of the screw. Therefore, if the screw head is not countersunk, the tip of the screw is 5 mm short of the tip of the guide pin (head height = 5 mm).



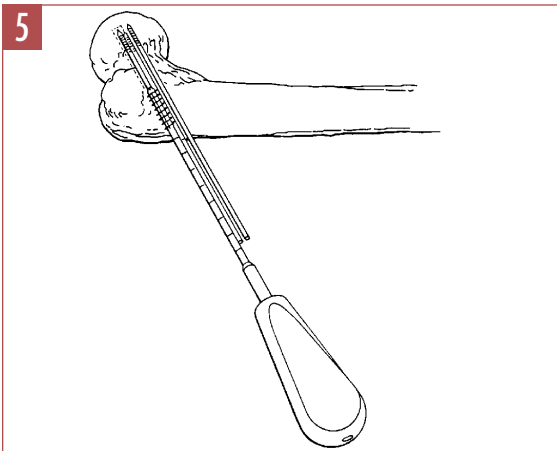
6.5 MM OPEN SURGICAL TECHNIQUE

(See next page for percutaneous technique.)



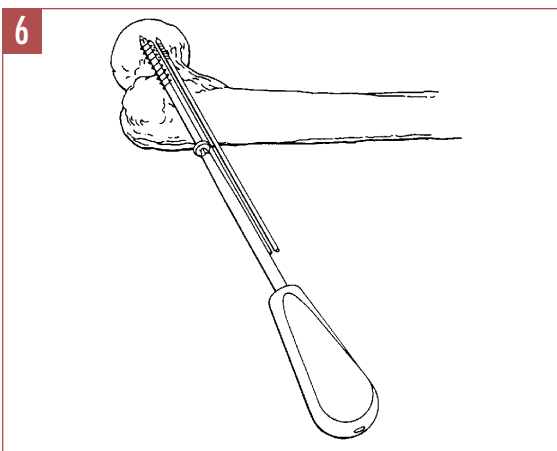
4 REAM —

The 4.8 mm Cannulated Reamer (11-0069) slips easily into the Quick-Chuck Adapter and is used to ream the hole for the screw. In soft bone, reaming for the entire length of the screw is unnecessary. Reaming 5 mm short of the screw measurement prevents the reamer from engaging the threaded tip of the guide pin, avoiding inadvertent guide pin removal.



5 TAP —

Use of the 6.5 mm Cannulated Screw Tap (11-0071) is optional, because the 6.5 mm Cannulated Screw is self-tapping. Tapping enables the screw to pass smoothly through the near cortex, so reduction can be maintained.



6 INSERT SCREW —

The 6.5 mm Cannulated Screwdriver with Countersink (11-0120) has a built-in countersink to create a recess in the bone for low profile seating of the screw head. After countersinking, the appropriate length screw is loaded onto the screwdriver and inserted over the guide pin into the bone.

Repeat steps 3 through 6 for placement of multiple screws.

ALTERNATIVE TECHNIQUE

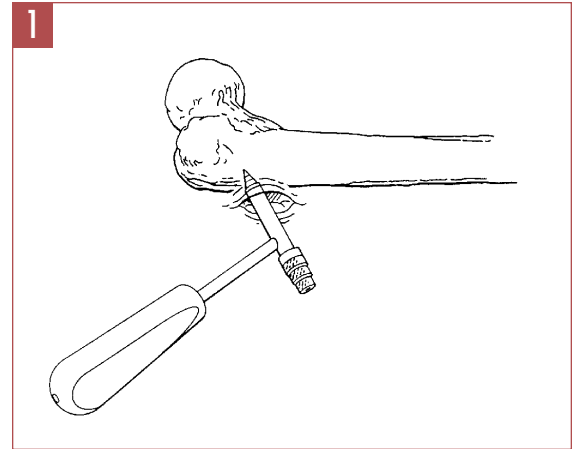
The 6.5 mm Cannulated Screw can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

6.5 MM PERCUTANEOUS SURGICAL TECHNIQUE

(See previous page for open technique.)

1 INSERT STACKED SLEEVES THROUGH SOFT TISSUES –

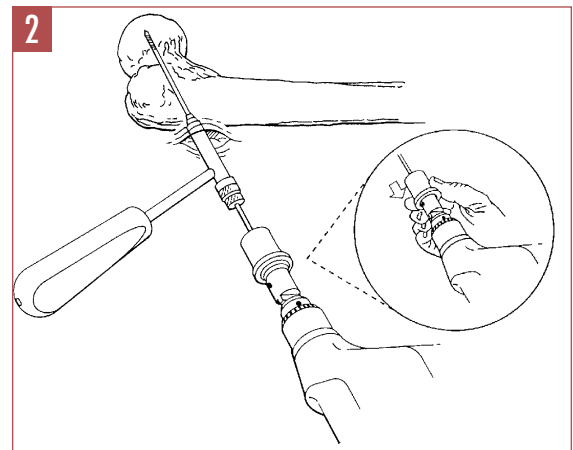
The percutaneous stacked sleeve assembly is inserted through the soft tissues and placed against the cortex. All of the surgical steps can be performed through the stacked sleeves, which include the outer 8.0 mm Drill Sleeve (7111-0300), 4.8 mm Black Drill Sleeve (7111-0301), 2.4 mm Red Drill Sleeve (7111-0302), and a 2.4 mm Trocar (7111-0303). Once the sleeve assembly is placed against the cortex, the 2.4 mm Trocar can be tapped with a mallet to dimple the bone.



2 INSERT GUIDE PIN –

The 2.4 mm Trocar is removed. The 2.4 mm Guide Pin (41-0236) slips into the 6.5 mm Quick-Chuck Adapter (7111-0306)* by pulling back the cap on the adapter. The guide pin is then inserted through the 2.4 mm Red Drill Sleeve and advanced into bone. When removing the instruments from the adapter, it may be necessary to first rotate the power source 90° counterclockwise.

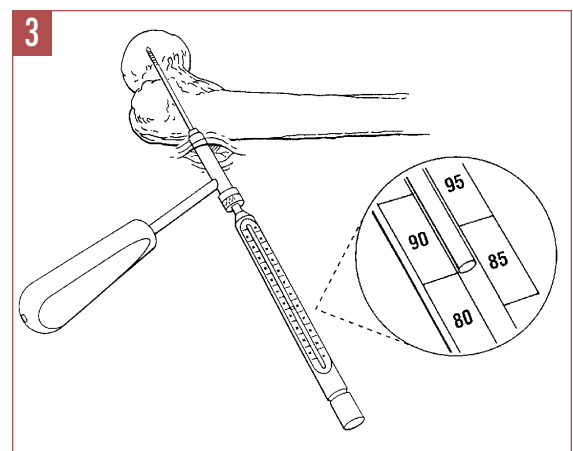
**The 6.5 mm Quick-Chuck Adapter is compatible with Amsco Hall, Jacobs, and Stryker power equipment.*



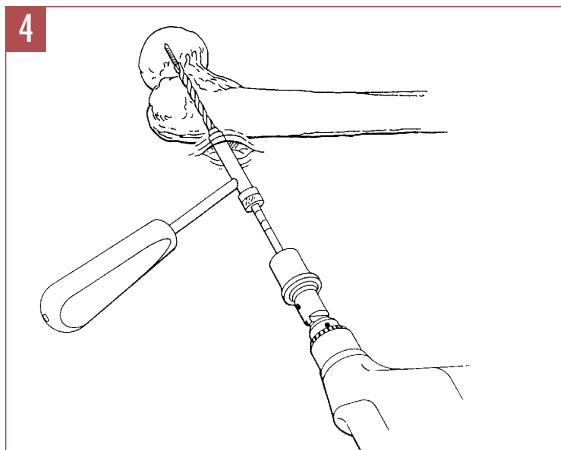
3 MEASURE –

The 2.4 mm Red Drill Sleeve is removed. The Direct Measuring Gauge (7111-0308) is placed over the guide pin and inserted through the 4.8 mm Black Drill Sleeve. The gauge is positioned directly against bone for accurate measurement. Screw length measurement is read from the back of the guide pin.

Note: The Direct Measuring Gauge is calibrated to display the actual length of guide pin within the bone. Overall screw lengths of the 6.5 mm Cannulated Screw are measured from the top of the head to the tip of the screw. Therefore, if the screw head is not countersunk, the tip of the screw is 5 mm short of the tip of the guide pin (head height = 5 mm).

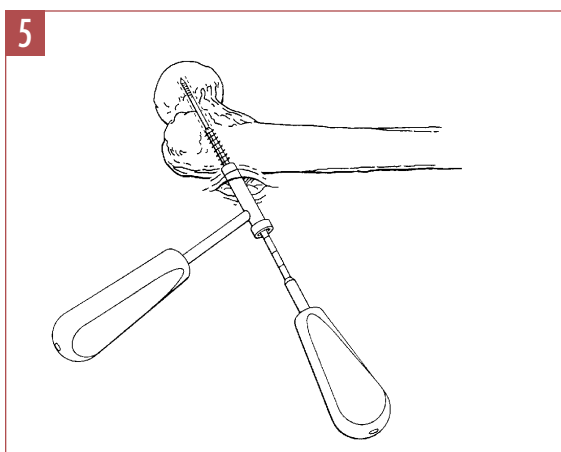


6.5 MM PERCUTANEOUS SURGICAL TECHNIQUE



4 REAM –

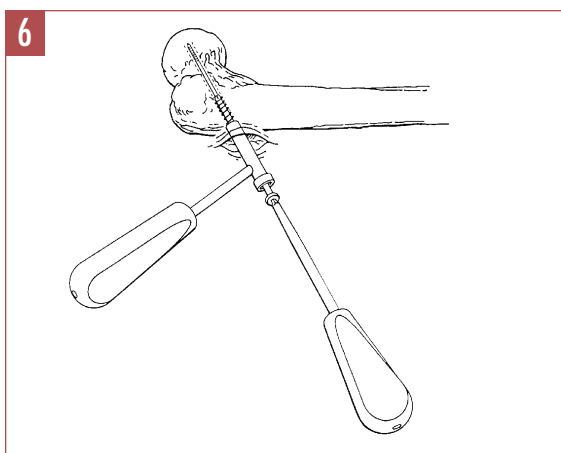
The 4.8 mm Cannulated Reamer (11-0069) slips easily into the Quick-Chuck Adapter. The reamer is used through the 4.8 mm Black Drill Sleeve to ream the hole for the screw. In soft bone, reaming for the entire length of the screw is unnecessary. Reaming 5 mm short of the screw measurement prevents the reamer from engaging the threaded tip of the guide pin, avoiding inadvertent guide pin removal.



5 TAP –

The 4.8 mm Black Drill Sleeve is removed. Use of the 6.5 mm Cannulated Screw Tap (11-0071) is optional, because the 6.5 mm Cannulated Screw is self-tapping. Tapping is performed through the outer 8.0 mm Drill Sleeve. Tapping enables the screw to pass smoothly through the near cortex, so reduction can be maintained.

Note: The calibrations on the Cannulated Reamer and Cannulated Screw Tap are not calibrated for the percutaneous stacked sleeves.



6 INSERT SCREW –

Both countersinking and screw insertion are performed through the outer 8.0 mm Drill Sleeve. The 6.5 mm Cannulated Screwdriver with Countersink (11-0120) has a built-in countersink, used to create a recess in the bone for low profile seating of the screw head. After countersinking, the appropriate length screw is loaded onto the screwdriver and inserted over the guide pin into the bone.

ALTERNATIVE TECHNIQUE

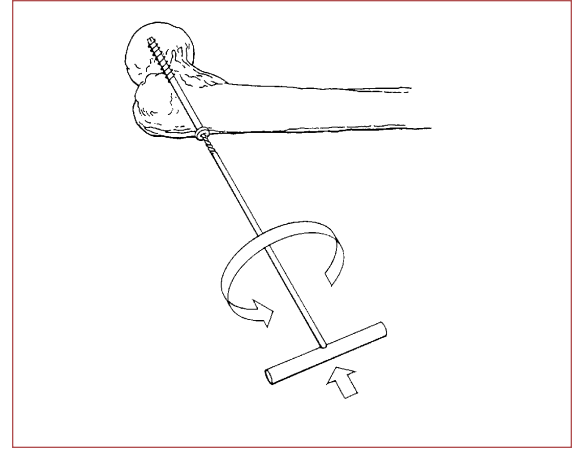
The 6.5 mm Cannulated Screw can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

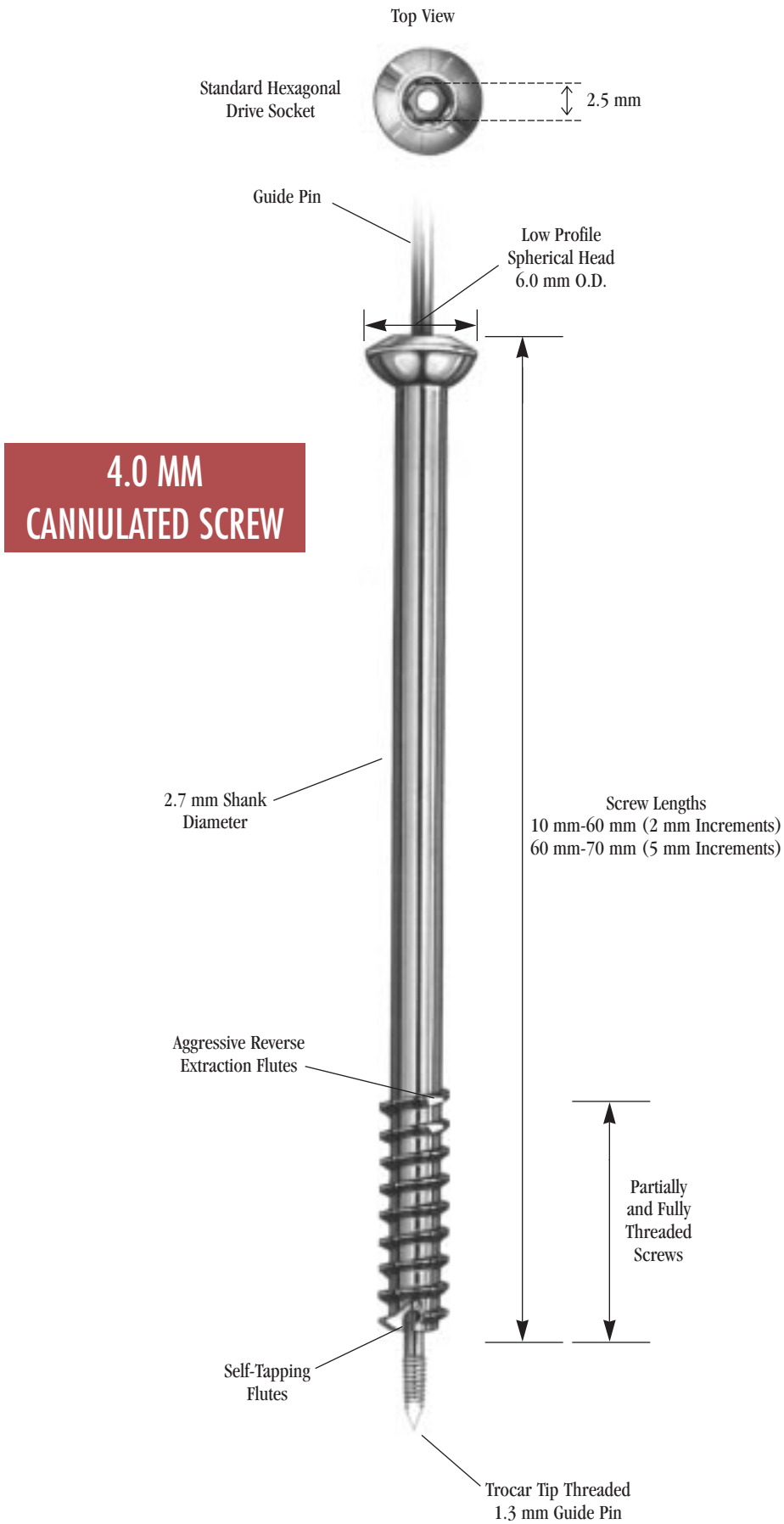
6.5 MM SCREW REMOVAL

SCREW EXTRACTION —

Screw extraction should be performed with the 3.5 mm Solid Hex Screwdriver (11-5035). The 6.5 mm Cannulated Screwdriver with Countersink (11-0120) should not be used for screw removal.

If complications arise during screw extraction, the screw can be removed with the 6.5 mm Cannulated Screw Extractor (7111-0307). The Extractor is tapped lightly into the cannulation of the screw with a mallet. The Extractor is then turned counterclockwise and bores into the inner wall of the screw to facilitate removal.





4.0 MM SURGICAL TECHNIQUE

1 INSERT GUIDE PIN –

The 1.3 mm Drill Sleeve (11-7076) is inserted into the 4.0 mm Drill Sleeve (11-7077). This sleeve assembly is inserted through the soft tissues and placed against the near cortex. The 1.3 mm Guide Pin (12-8047 or 12-8039) slips into the 4.0 mm Quick-Chuck Adapter (7111-7082)* by pulling back the cap on the adapter. The guide pin is inserted through the sleeves and advanced into bone. When removing the instruments from the adapter, it may be necessary to first rotate the power source 90° counterclockwise.

**The 4.0 mm Quick-Chuck Adapter is compatible with Amsco Hall, Jacobs, and Stryker power equipment.*

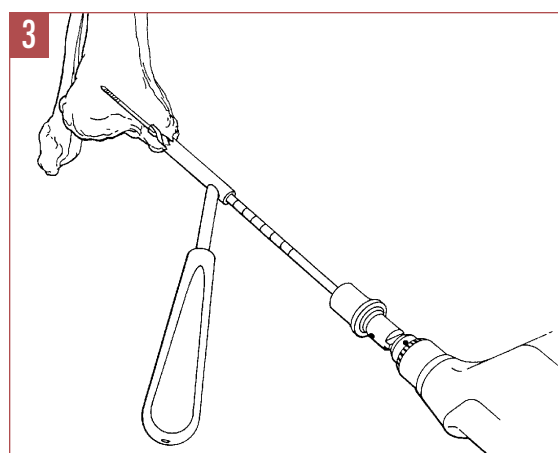
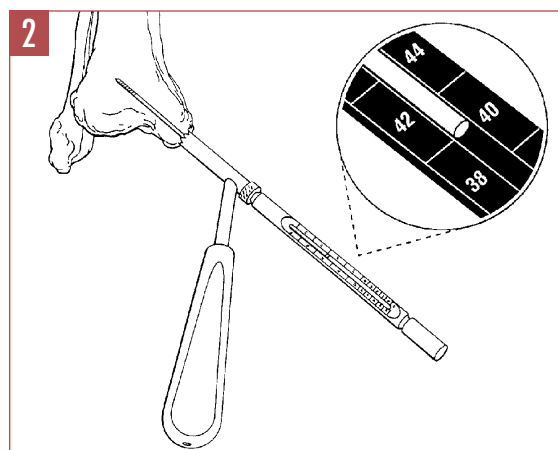
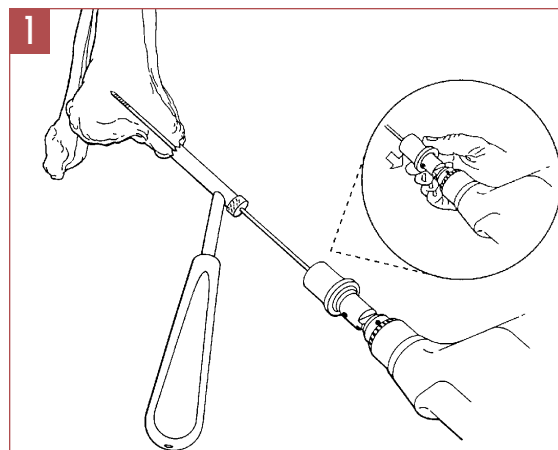
2 MEASURE –

The 4.0 mm Cannulated Screw Sleeve Measuring Gauge (11-7072) is placed against the back of the 1.3 mm Drill Sleeve to determine the length of screw needed. Screw length measurement is read from the back of the guide pin.

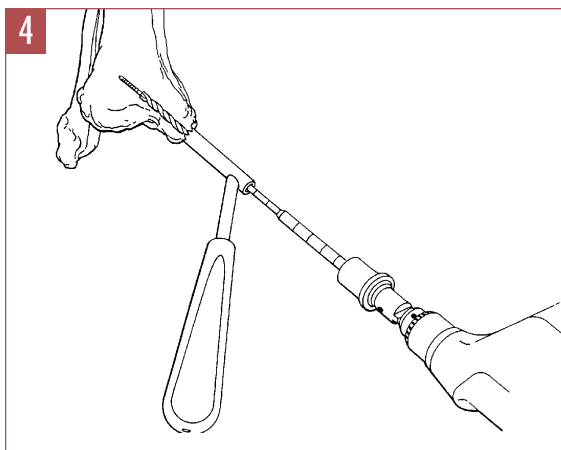
Note: The 4.0 mm Cannulated Screw Sleeve Measuring Gauge is calibrated to display the actual length of guide pin within the bone. Overall screw lengths of the 4.0 mm Cannulated Screw are measured from the top of the head to the tip of the screw. Therefore, if the screw head is not countersunk, the tip of the screw is 3 mm short of the tip of the guide pin (head height = 3 mm).

3 REAM CORTEX –

Remove the 1.3 mm Drill Sleeve from the 4.0 mm Drill Sleeve. The 4.0 mm Cannulated Cortex Reamer (11-7067) slips into the 4.0 mm Quick-Chuck Adapter and can be used through the 4.0 mm Drill Sleeve. Use of the cortex reamer is optional. The cortex reamer is 4 mm in diameter, and is used to ream the near cortex only. Its purpose is two-fold: to prolong the cutting life of the 2.7 mm Cannulated Screw Reamer, and to overdrill the near cortex and lag fragments with a fully threaded 4.0 mm Cannulated Screw.

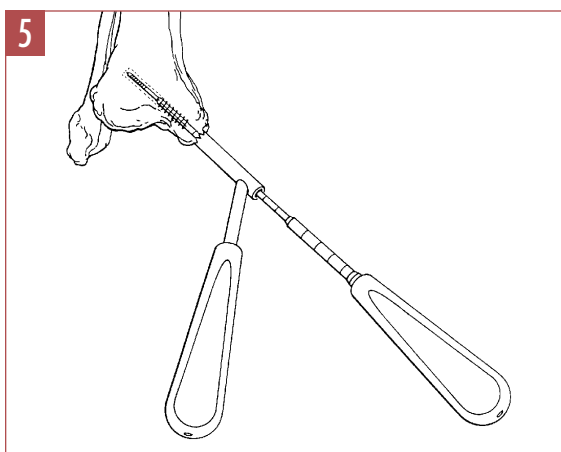


4.0 MM SURGICAL TECHNIQUE



4 REAM –

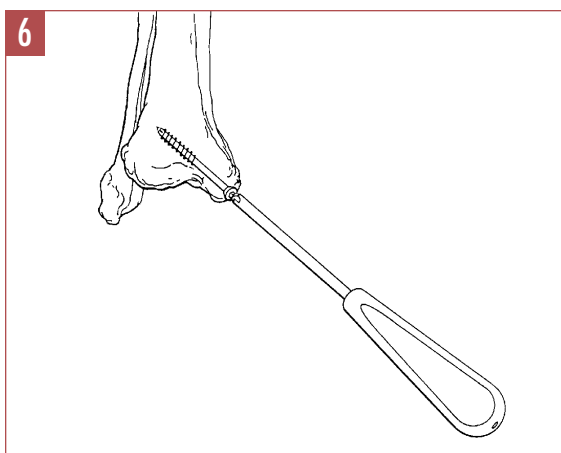
The 2.7 mm Cannulated Screw Reamer (11-7066) slips into the Quick-Chuck Adapter and is used through the 4.0 mm Drill Sleeve to ream the hole for the screw. In soft bone, reaming for the entire length of the screw is unnecessary. Reaming 5 mm short of the screw measurement prevents the reamer from engaging the threaded tip of the guide pin, avoiding inadvertent guide pin removal.



5 TAP –

Use of the 4.0 mm Cannulated Screw Tap (11-7079) is optional, because the 4.0 mm Cannulated Screw is self-tapping. Tapping is performed through the 4.0 mm Drill Sleeve. Tapping enables the screw to pass smoothly through the near cortex, so reduction can be maintained.

Note: All of the calibrations on the instruments are read from the back of the 4.0 mm drill sleeve.



6 INSERT SCREW –

Remove the 4.0 mm Drill Sleeve. The 4.0 mm Cannulated Screwdriver with Countersink (11-7070) has a built-in countersink, used to create a recess in the bone for low profile seating of the screw head. After countersinking, the appropriate length screw is loaded onto the screwdriver and inserted over the guide pin into the bone.

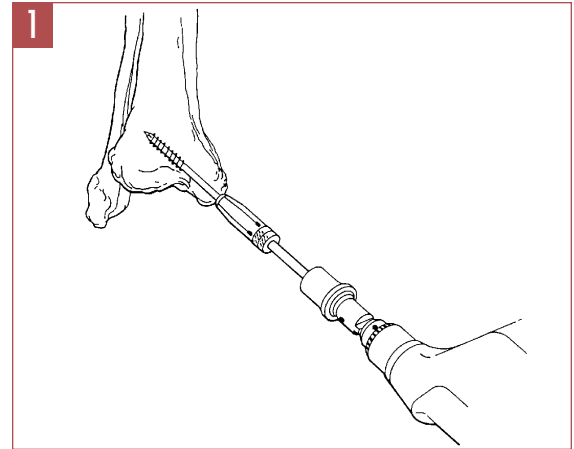
ALTERNATIVE TECHNIQUE

The 4.0 mm Cannulated Screw can be inserted over the guide pin without predrilling or pretapping. In dense bone, however, predrilling and pretapping are recommended to facilitate screw insertion.

4.0 MM TECHNIQUE OPTIONS

1 POWER INSERTION OF SCREWS —

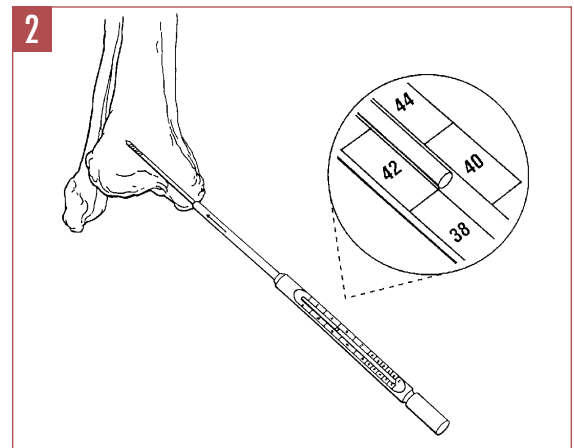
The Self-Holding Screwdriver (7111-7081) slips easily into the Quick-Chuck Adapter and can be used for power insertion of 4.0 mm Cannulated Screws. The Cannulated Screwdriver should always be used for final, manual seating of the screw.



2 DIRECT MEASURE —

The 4.0 mm Cannulated Screw Direct Measuring Gauge (7111-7083) can be placed over the guide pin and directly against bone to determine screw length. Screw length measurement is read from the back of the guide pin.

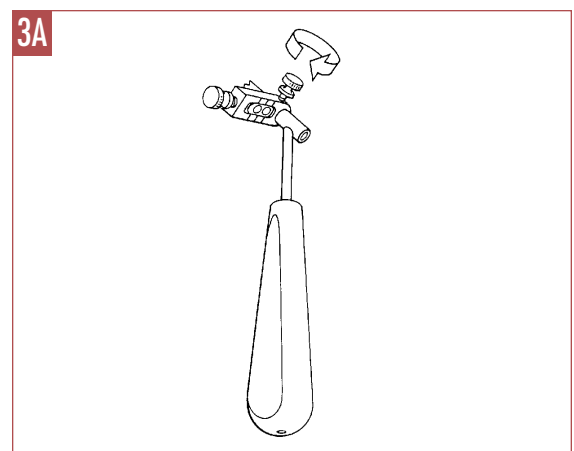
Note: The 4.0 mm Cannulated Screw Direct Measuring Gauge is calibrated to display the actual length of guide pin within the bone. Overall screw lengths of the 4.0 mm Cannulated Screw are measured from the top of the head to the tip of the screw. Therefore, if the screw head is not counter-sunk, the tip of the screw is 3 mm short of the tip of the guide pin (head height = 3 mm).

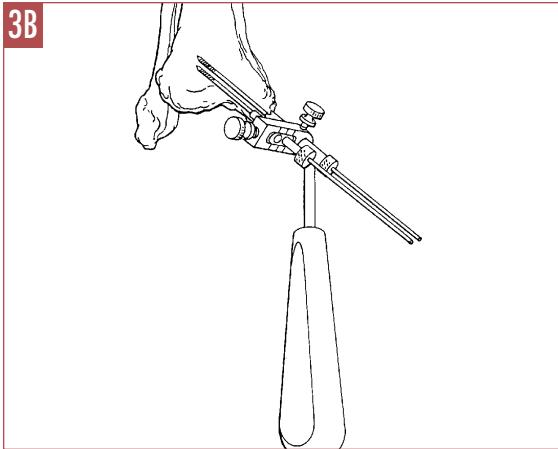


3A INSERT PARALLEL PINS —

The 1.3 mm Parallel Pin Guide (7111-7080) can be used to place multiple parallel pins. The 1.3 mm Parallel Pin Guide slips onto the 4.0 mm Drill Sleeve and is tightened down with a twist knob. The pin guide can be rotated and placed in any plane — up, down, and around the drill sleeve. Within the pin guide, the sliding block can be set at fixed distances from 8 mm to 20 mm.

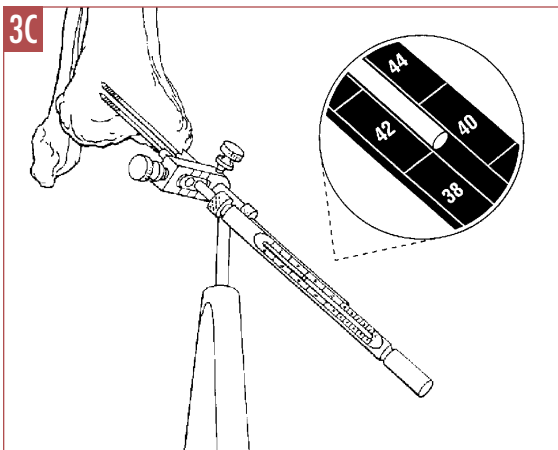
Note: To ensure a smoother, more simplistic surgical procedure, the Parallel Pin Guide should be placed onto the 4.0 mm Drill Sleeve prior to inserting the initial guide pin.





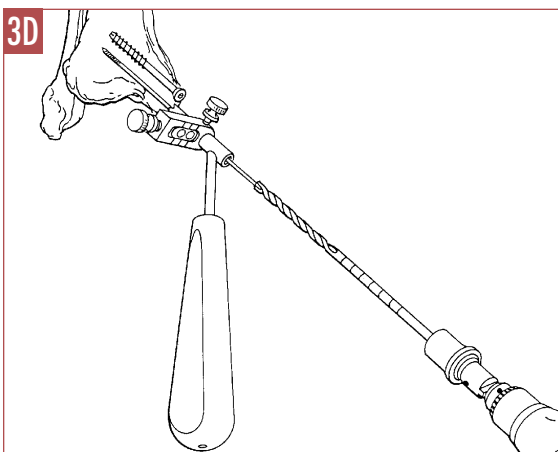
3B The 1.3 mm Drill Sleeve is inserted into one of the holes in the 1.3 mm Parallel Pin Guide. A guide pin can be advanced through the drill sleeve into the bone.

Note: It is not necessary that the 1.3 mm Drill Sleeve snap into the hole in the 1.3 mm Parallel Pin Guide, but the drill sleeve must contact bone for accurate measurement.



3C The screw length can be determined with the 4.0 mm Cannulated Screw Sleeve Measuring Gauge. The gauge is placed directly against the back of the 1.3 mm Drill Sleeve to make the measurement. Screw length measurement is read from the back of the guide pin.

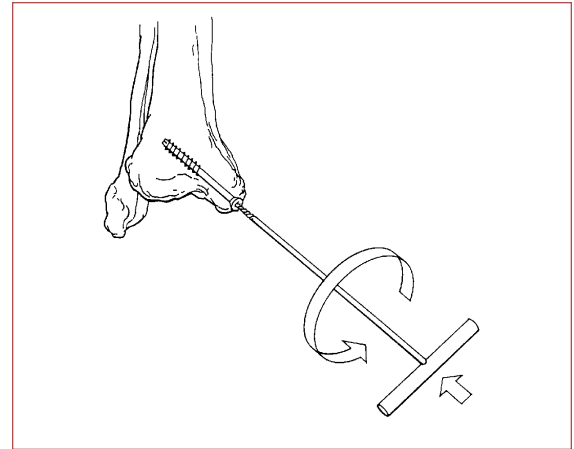
3D After the initial screw has been inserted over the initial guide pin, the 4.0 mm Drill Sleeve can be placed over the 1.3 mm Parallel Pin Guide to protect the soft tissues while reaming and tapping for the parallel screw.



4.0 MM SCREW REMOVAL

SCREW EXTRACTION —

Screw extraction is performed with the 4.0 mm Cannulated Screwdriver with Countersink. The screwdriver has a 2.5 mm hexagonal tip. If complications arise during screw extraction, the screw can be removed with the 4.0 mm Cannulated Screw Extractor (7111-7084). The Extractor is tapped lightly into the cannulation of the screw with a mallet. The Extractor is then turned counter-clockwise and bores into the inner wall of the screw to facilitate removal.



6.5 MM CANNULATED SCREWS

Titanium (Nonsterile Packaged)

20 mm Thread Length

Cat. No.	Screw Length
7116-1040	40 mm
7116-1045	45 mm
7116-1050	50 mm
7116-1055	55 mm
7116-1060	60 mm
7116-1065	65 mm
7116-1070	70 mm
7116-1075	75 mm
7116-1080	80 mm
7116-1085	85 mm
7116-1090	90 mm
7116-1095	95 mm
7116-1100	100 mm
7116-1105	105 mm
7116-1110	110 mm



20 mm Thread Length



32 mm Thread Length



6.5 mm CANNULATED SCREWS

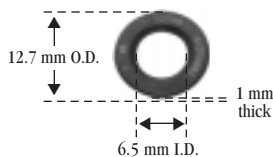
Stainless Steel (Sterile Packaged)

Cat. No.	Screw Length	Thread Length
12-1625	25 mm	16 mm
12-1626	30 mm	16 mm
12-1627	35 mm	20 mm
12-1628	40 mm	20 mm
12-1629	45 mm	20 mm
12-1630	50 mm	20 mm
12-1631	55 mm	20 mm
12-1632	60 mm	20 mm
12-1633	65 mm	20 mm
12-1634	70 mm	20 mm
12-1635	75 mm	20 mm
12-1636	80 mm	20 mm
12-1637	85 mm	20 mm
12-1638	90 mm	20 mm
12-1639	95 mm	20 mm
12-1640	100 mm	20 mm
12-1641	105 mm	20 mm
12-1642	110 mm	20 mm
12-1643	115 mm	20 mm
12-1644	120 mm	20 mm
7110-0045	45 mm	32 mm
7110-0050	50 mm	32 mm
7110-0055	55 mm	32 mm
7110-0060	60 mm	32 mm
7110-0065	65 mm	32 mm
7110-0070	70 mm	32 mm
7110-0075	75 mm	32 mm
7110-0080	80 mm	32 mm
7110-0085	85 mm	32 mm
7110-0090	90 mm	32 mm
7110-0095	95 mm	32 mm
7110-0100	100 mm	32 mm
7110-0105	105 mm	32 mm
7110-0110	110 mm	32 mm
7110-0115	115 mm	32 mm
7110-0120	120 mm	32 mm
7110-0125	125 mm	32 mm
7110-0130	130 mm	32 mm

6.5 MM TITANIUM WASHER

(Sterile Packaged) 6 per box

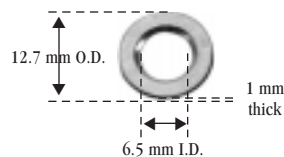
Cat. No. 7110-2000



6.5 MM STAINLESS STEEL WASHER

(Sterile Packaged) 6 per box

Cat. No. 12-1680



6.5 MM INSTRUMENTS

6.5 mm Quick-Chuck Adapter

(mates with Amsco Hall, Stryker,
and Jacobs power equipment)
Cat. No. 7111-0306



4.7 mm Twist Drill

Cat. No. 21-0446



8.0 mm Drill Sleeve

Cat. No. 7111-0300



4.8 mm Drill Sleeve (Black)

Cat. No. 7111-0301



2.4 mm Drill Sleeve (Red)

Cat. No. 7111-0302



2.4 mm Trocar

Cat. No. 7111-0303



Guide Pin 2.4 mm x 230 mm

(Nonsterile Packaged) 6 per box
Cat. No. 41-0236



6.5 mm Cannulated Screw Direct Measuring Gauge

Cat. No. 7111-0308



6.5 mm Cannulated Screw Parallel Pin Guide

Cat. No. 7111-0305



4.8 mm Cannulated Reamer

Cat. No. 11-0069





6.5 mm Cannulated Screw Tap
Cat. No. 11-0071



Cannulated Screwdriver with Countersink
(for insertion only)
Cat. No. 11-0120



3.5 mm Solid Hex Screwdriver
(for extraction only)
Cat. No. 11-5035



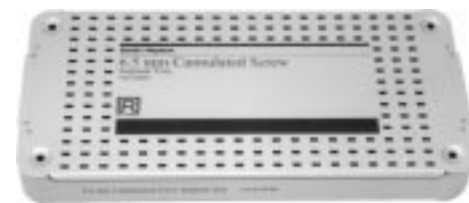
6.5 mm Cannulated Screw Extractor
Cat. No. 7111-0307



Obturator
Cat. No. 11-6500



6.5 mm Cannulated Screw Instrument Tray
Cat. No. 7111-0309



6.5 mm Cannulated Stainless Steel
Screw Implant Tray
Cat. No. 7111-0310



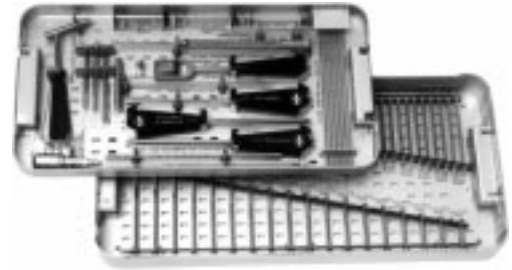
Sterile Pack – Typical

6.5 MM CANNULATED SCREW SETS

6.5 mm Cannulated Screw System Set

Cat. No. 7111-0311

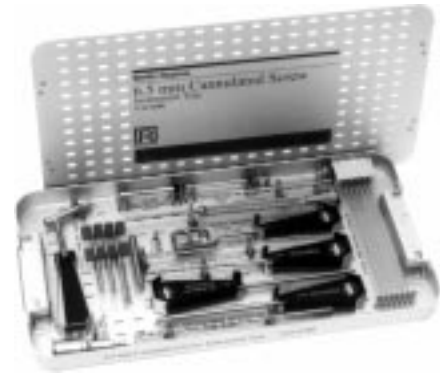
Cat. No.	Description	Qty.
7111-0306	6.5 mm Quick-Chuck Adapter	1
21-0446	4.7 mm Twist Drill	1
7111-0300	8.0 mm Drill Sleeve	1
7111-0301	4.8 mm Drill Sleeve (Black)	1
7111-0302	2.4 mm Drill Sleeve (Red)	1
7111-0303	2.4 mm Trocar	1
41-0236	Guide Pin 2.4 mm x 230 mm	6
7111-0308	6.5 mm Cannulated Screw Direct Measuring Gauge	1
7111-0305	6.5 mm Cannulated Screw Parallel Pin Guide	1
11-0069	4.8 mm Cannulated Reamer	1
11-0071	6.5 mm Cannulated Screw Tap	1
11-0120	6.5 mm Cannulated Screwdriver with Countersink	1
11-5035	Solid 3.5 mm Hex Screwdriver	1
7111-0307	6.5 mm Cannulated Screw Extractor	1
11-6500	Obturator	1
12-1680	6.5 mm Washer	6
7111-0309	6.5 mm Cannulated Screw Instrument Tray	1
7111-0310	6.5 mm Cannulated Stainless Steel Screw Implant Tray	1
12-1625–12-1626	6.5 mm Cannulated Stainless Steel Screw, 16 mm Thread, 25-30 mm	2 ea.
12-1627–12-1644	6.5 mm Cannulated Stainless Steel Screw, 20 mm Thread, 35-120 mm	2 ea.
7110-0045– 7110-0130	6.5 mm Cannulated Stainless Steel Screw, 32 mm Thread, 45-130 mm	1 ea.



6.5 mm Cannulated Screw Instrument Set

Cat. No. 7111-0312

Cat. No.	Description	Qty.
7111-0306	6.5 mm Quick-Chuck Adapter	1
21-0446	4.7 mm Twist Drill	1
7111-0300	8.0 mm Drill Sleeve	1
7111-0301	4.8 mm Drill Sleeve (Black)	1
7111-0302	2.4 mm Drill Sleeve (Red)	1
7111-0303	2.4 mm Trocar	1
41-0236	Guide Pin 2.4 mm x 230 mm	6
7111-0308	6.5 mm Cannulated Screw Direct Measuring Gauge	1
7111-0305	6.5 mm Cannulated Screw Parallel Pin Guide	1
11-0069	4.8 mm Cannulated Reamer	1
11-0071	6.5 mm Cannulated Screw Tap	1
11-0120	6.5 mm Cannulated Screwdriver with Countersink	1
11-5035	Solid 3.5 mm Hex Screwdriver	1
7111-0307	6.5 mm Cannulated Screw Extractor	1
11-6500	Obturator	1
7111-0309	6.5 mm Cannulated Screw Instrument Tray	1



6.5 mm Cannulated Stainless Steel Screw Implant Set

32 mm Thread Length

Cat. No. 7110-0200

Cat. No.	Description	Qty.
7110-0045–7110-0130	6.5 mm Cannulated Screw, 45-130 mm	1 ea.
12-1680	6.5 mm Stainless Steel Washer	6

6.5 mm Cannulated Titanium Screw Implant Set

20 mm Thread Length

Cat. No. 7110-0004

Cat. No.	Description	Qty.
7116-1040–7116-1110	6.5 mm Cannulated Screw, 40-110 mm	2 ea.
7110-2000	6.5 mm Titanium Washer	6

4.0 MM CANNULATED SCREWS

Titanium — Partially Threaded
(Sterile Packaged)

Cat. No.	Screw Length	Thread Length
7110-1020	20 mm	8 mm
7110-1022	22 mm	9 mm
7110-1024	24 mm	10 mm
7110-1026	26 mm	12 mm
7110-1028	28 mm	14 mm
7110-1030	30 mm	14 mm
7110-1032	32 mm	14 mm
7110-1034	34 mm	14 mm
7110-1036	36 mm	14 mm
7110-1038	38 mm	14 mm
7110-1040	40 mm	14 mm
7110-1042	42 mm	14 mm
7110-1044	44 mm	15 mm
7110-1046	46 mm	15 mm
7110-1048	48 mm	15 mm
7110-1050	50 mm	15 mm
7110-1052	52 mm	15 mm
7110-1054	54 mm	15 mm
7110-1056	56 mm	15 mm
7110-1058	58 mm	15 mm
7110-1060	60 mm	15 mm
7110-1065	65 mm	15 mm
7110-1070	70 mm	15 mm



4.0 MM CANNULATED SCREWS

Stainless Steel — Partially Threaded
(Sterile Packaged)

Cat. No.	Screw Length	Thread Length
12-1810	10 mm	5 mm
12-1812	12 mm	5 mm
12-1814	14 mm	5 mm
12-1816	16 mm	6 mm
12-1818	18 mm	7 mm
12-1820	20 mm	8 mm
12-1822	22 mm	9 mm
12-1824	24 mm	10 mm
12-1826	26 mm	12 mm
12-1828	28 mm	14 mm
12-1830	30 mm	14 mm
12-1832	32 mm	14 mm
12-1834	34 mm	14 mm
12-1836	36 mm	14 mm
12-1838	38 mm	14 mm
12-1840	40 mm	14 mm
12-1842	42 mm	14 mm
12-1844	44 mm	15 mm
12-1846	46 mm	15 mm
12-1848	48 mm	15 mm
12-1850	50 mm	15 mm
12-1852	52 mm	15 mm
12-1854	54 mm	15 mm
12-1856	56 mm	15 mm
12-1858	58 mm	15 mm
12-1860	60 mm	15 mm
12-1865	65 mm	15 mm
12-1870	70 mm	15 mm

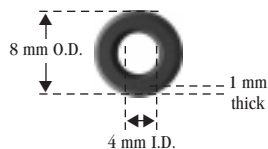
Stainless Steel — Fully Threaded
(Sterile Packaged)

Cat. No.	Screw Length
22-2820	20 mm
22-2822	22 mm
22-2824	24 mm
22-2826	26 mm
22-2828	28 mm
22-2830	30 mm
22-2835	35 mm
22-2840	40 mm
22-2845	45 mm
22-2850	50 mm
22-2855	55 mm
22-2860	60 mm
22-2865	65 mm
22-2870	70 mm



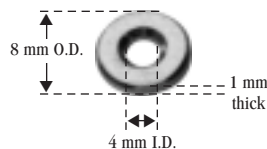
4.0 MM TITANIUM WASHER

(Sterile Packaged) 6 per box
Cat. No. 7110-1000



4.0 MM STAINLESS STEEL WASHER

(Sterile Packaged) 6 per box
Cat. No. 7112-0006



4.0 MM INSTRUMENTS

4.0 mm Quick-Chuck Adapter

(mates with Amsco Hall, Stryker, and Jacobs power equipment)
 Cat. No. 7111-7082



4.0 mm Drill Sleeve

Cat. No. 11-7077



1.3 mm Drill Sleeve

Cat. No. 11-7076



1.3 mm Parallel Pin Guide

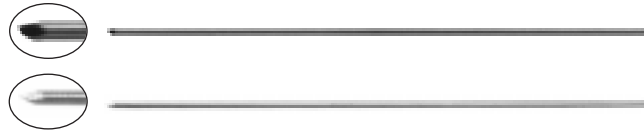
Cat. No. 7111-7080



1.3 mm Guide Pin

(Sterile Packaged) 6 per box

Cat. No.	Description
12-8039	Bayonet Point
12-8047	Tip Threaded



4.0 mm Cannulated Screw Sleeve Measuring Gauge

Cat. No. 11-7072



4.0 mm Cannulated Screw Direct Measuring Gauge

Cat. No. 7111-7083



4.0 mm Cannulated Cortex Reamer

Cat. No. 11-7067





2.7 mm Cannulated Screw Reamer
Cat. No. 11-7066



4.0 mm Cannulated Screw Tap
Cat. No. 11-7079



Self-Holding Screwdriver
Cat. No. 7111-7081



4.0 mm Cannulated Screwdriver
with Countersink
Cat. No. 11-7070



4.0 mm Cannulated Screw Extractor
Cat. No. 7111-7084



Obturator
Cat. No. 11-6501



4.0 mm Cannulated Screw Instrument Tray
Cat. No. 7111-7085



4.0 mm Cannulated Stainless Steel
Screw Implant Tray
Cat. No. 7111-7086



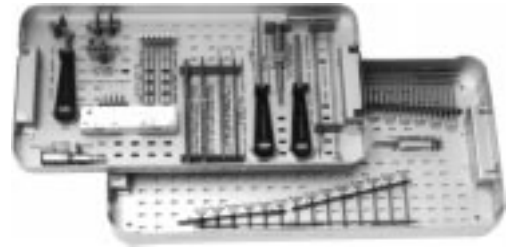
Sterile Pack – Typical

4.0 MM CANNULATED SCREW SETS

4.0 mm Cannulated Screw System Set

Cat. No. 7111-7089

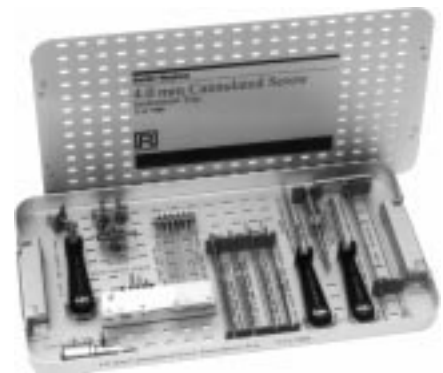
Cat. No.	Description	Qty.
7111-7082	4.0 mm Quick-Chuck Adapter	1
11-7077	4.0 mm Drill Sleeve	1
11-7076	1.3 mm Drill Sleeve	2
7111-7080	1.3 mm Parallel Pin Guide	1
12-8039	1.3 mm Guide Pin, Bayonet Point	6
12-8047	1.3 mm Guide Pin, Tip Threaded	6
11-7072	4.0 mm Cannulated Screw Sleeve Measuring Gauge	1
7111-7083	4.0 mm Cannulated Screw Direct Measuring Gauge	1
11-7067	4.0 mm Cannulated Cortex Reamer	1
11-7066	2.7 mm Cannulated Reamer	1
11-7079	4.0 mm Cannulated Screw Tap	1
7111-7081	Self-Holding Screwdriver	1
11-7070	4.0 mm Cannulated Screwdriver with Countersink	1
7111-7084	4.0 mm Cannulated Screw Extractor	1
11-6501	Obturator	1
A390014	4.0 mm Washer	6
7111-7085	4.0 mm Cannulated Screw Instrument Tray	1
7111-7086	4.0 mm Cannulated Screw Implant Tray	1
12-1810–12-1870	4.0 mm Cannulated Stainless Steel Screw, Partially Threaded, 10-70 mm	3 ea.
22-2820–22-2870	4.0 mm Cannulated Stainless Steel Screw, Fully Threaded, 20-70 mm	1 ea.



4.0 mm Cannulated Screw Instrument Set

Cat. No. 7111-7090

Cat. No.	Description	Qty.
7111-7082	4.0 mm Quick-Chuck Adapter	1
11-7077	4.0 mm Drill Sleeve	1
11-7076	1.3 mm Drill Sleeve	2
7111-7080	1.3 mm Parallel Pin Guide	1
12-8039	1.3 mm Guide Pin, Bayonet Point	6
12-8047	1.3 mm Guide Pin, Tip Threaded	6
11-7072	4.0 mm Cannulated Screw Sleeve Measuring Gauge	1
7111-7083	4.0 mm Cannulated Screw Direct Measuring Gauge	1
11-7067	4.0 mm Cannulated Cortex Reamer	1
11-7066	2.7 mm Cannulated Reamer	1
11-7079	4.0 mm Cannulated Screw Tap	1
7111-7081	Self-Holding Screwdriver	1
11-7070	4.0 mm Cannulated Screwdriver with Countersink	1
7111-7084	4.0 mm Cannulated Screw Extractor	1
11-6501	Obturator	1
7111-7085	4.0 mm Cannulated Screw Instrument Tray	1



4.0 mm Cannulated Stainless Steel Screw Implant Set

Fully Threaded

Cat. No. 7110-0201

Cat. No.	Description	Qty.
22-2820–22-2870	4.0 mm Cannulated Screw, 20–70 mm	1 ea.
7112-0006	4.0 mm Washer	6

4.0 mm Cannulated Titanium Screw Implant Set

Partially Threaded

Cat. No. 7110-0001

Cat. No.	Description	Qty.
7110-1020–7110-1070	4.0 mm Cannulated Screw, 20–70 mm	4 ea.
7112-1000	4.0 mm Titanium Washer	6

IMPORTANT MEDICAL INFORMATION

SMITH & NEPHEW COMPRESSION HIP SCREWS CANNULATED/BONE SCREWS BONE PLATES, PINS, WIRES FRACTURE FIXATION DEVICES

SPECIAL NOTE

Fracture fixation devices are used only as an aid to healing, they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws or barrel plates and thus the strength of implants is limited. Full weight bearing prior to complete bone healing is contraindicated. With repeated stress in patients with delayed healing or nonunion, the appliance will inevitably bend, break or pull out of bone.

Fracture fixation devices are available in many styles and sizes and are made from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. All implantable devices are designed for single use only.

INDICATIONS

Bone Plates, Screws, Pins and Wires

Bone plates, screws, pins and wires are indicated for pelvic, small and long bone fracture fixation. Refer to medical or manufacturer literature for specific product applications.

Compression Hip Screws/IMHS

1. Intracapsular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)
2. Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
3. Osteotomies for patients with diseases or deformities of the hip.
4. Hip arthrodesis.
5. Supracondylar fractures and distal femoral fractures using a supracondylar plate.
6. Ipsilateral femoral shaft/neck fractures (long IMHS only).

Pediatric and Intermediate Compression Hip Screws

1. Congenital coxa vara.
2. Congenital dislocation of the hip.
3. Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomeningocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
4. Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

CONTRAINDICATIONS

1. Physical conditions that would preclude adequate implant support or retard healing such as, blood supply impairment, insufficient bone quality or quantity, previous infection, obesity, severe bow or gross distortion of the femur.
2. Mental conditions that preclude cooperation with the rehabilitation regimen.

Additional Contraindications for Pediatric and Intermediate Compression Hip Screws

1. Fracture of the neck of the femur. The capital femoral epiphysis or trochanteric epiphysis should not be violated by the lag screw. Cessation of growth may take place.
2. Slipped upper epiphysis. The bones in the trochanteric area and in the center of the femoral neck are so dense and the target area in the head of the femur so small that other techniques are preferable.
3. The Pediatric Compression Hip Screw is also contraindicated for patients under the age of 2 or over the age of 6 years.

WARNINGS

1. This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
3. Because of unbalanced muscle forces, subtrochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
4. Subtrochanteric and comminuted trochanteric fractures and osteotomies place increased stresses on bone plates. Plate length should be increased to provide maximal fixation. The highest angle plate is recommended. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time for non- or limited weight bearing should be correspondingly increased until solid bony union occurs.

5. The threads of an implanted lag screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
6. Do not mix dissimilar metals. Use only stainless steel screws with stainless steel devices, Ti-6Al-4V screws with Ti-6Al-4V devices, and Ti-13Nb-13Zr screws with Ti-13Nb-13Zr devices.

PRECAUTIONS

1. Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
2. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
3. While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.
4. Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of implant components.
2. Loss of anatomic position with malunion may occur.
3. Infections, both deep and superficial, have been reported.
4. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
5. Leg length discrepancies and subsequent patient limp may occur.
6. Screw cutting through the femoral head (usually associated with osteoporotic bone), penetration of the joint by a lag screw with or without chondrolysis, and failure of a lag screw to slide in the barrel, especially with low angle plates and/or improper screw plate assembly have been reported.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
8. Penetration of a guide wire/screw into the pelvis can occur.
9. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
10. Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses [Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)] with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Smith+Nephew

Leadership in Worldwide Healthcare

Smith & Nephew, Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A.
(901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538

The following statement is required by the U.S. FDA.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.