Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (cwf)

FOLDER: K000080 - 282 pages

COMPANY: HOWMEDICA OSTEONICS CORP. (HOWMOSTEA)

PRODUCT: SCREW, FIXATION, BONE (HWC)

SUMMARY: Product: ASNIS III CANNULATED SCREW SYSTEM

DATE REQUESTED: Feb 26, 2016

DATE PRINTED: Feb 26, 2016

Note: Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-2970; Released by CDRH on 03/11/2016

K000080

APR 3 2000

510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
ASNIS III Cannulated Screw System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date Summary Prepared:

December 20, 1999

Device Identification

Proprietary Name:

Asnis III Cannulated Screw System

Common Name:

Cannulated Screws, Washers

Classification Name and Reference:

Smooth of Threaded Metallic Bone Fixation Fastener
21 CFR §888.3040
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
21 CFR §888.3030

Predicate Device Identification

The Asnis III Cannulated Screw System is substantially equivalent to the following marketed devices: Howmedica Asnis II 5.0 and 6.5 Cannulated Screw System, the Synthes 3.5, 4.0, 4.5 and 7.3mm Cannulated Screws, the ACE Medical 4.0, 5.0, 6.5 and 8.0mm Cannulated Screws, the Richards 4.0 Cannulated Screw, the Smith and Nephew 6.5mm Universal Cannulated Screw System and 8.0mm Cannulated Screw System, the AAP 4.0, 4.5, 5.0 and 7.5mm Cannulated Screws , Alphatec 3.5 and 4.0mm Cannulated Screws and Zimmer 4.0 and 5.0mm Cannulated Screws.

Device Description

The Asnis III Cannulated Screw System consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0mm. They are either fully or partially threaded. All screws are

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selfdrilling and selftapping. There are washers corresponding to the 4.0mm and the 5.0mm screws respectively and one washer fitting for both diameters, 6.5mm and 8.0mm.

Intended Use

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Materials

The subject components can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 and DIN 17443 for all diameters, or ASTM 1314 for the 6.5mm and 8.0mm diameters).

Statement of Technological Comparison

The subject components of the ASNIS III Cannulated Screw System are substantially equivalent in design and intended use to the predicate devices offered by Howmedica Osteonics Corp., Synthes, ACE Medical, Richards, Smith and Nephew, Alphatec, and Zimmer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 2000

Ms. Mary-Catherine Dillon
Regulatory Affairs Team Member
Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

Re: K000080
ASNIS III Cannulated Screw System
Regulatory Class: II
Product Codes: HWC and HTN
Dated: January 10, 2000
Received: January 11, 2000

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Neil R.P. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

510(k) Number (if known): K 000080

Device Name: ASNIS III Cannulated Screw System

Indications For Use:

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

MRO for cmw

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000080

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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9200 Corporate Boulevard
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Regulatory Affairs Team Member
Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

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Sincerely yours,

Neil R.P. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
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Enclosure

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510(k) Number (if known): K 000080

Device Name: ASNIS III Cannulated Screw System

Indications For Use:

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

MRO for cmw
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000080

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Jamie Allen 3/30/00

Subject: 510(k) Number K000080

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☒ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: HWC 87/II

Additional Product Code(s) with panel (optional): HTN 87/II

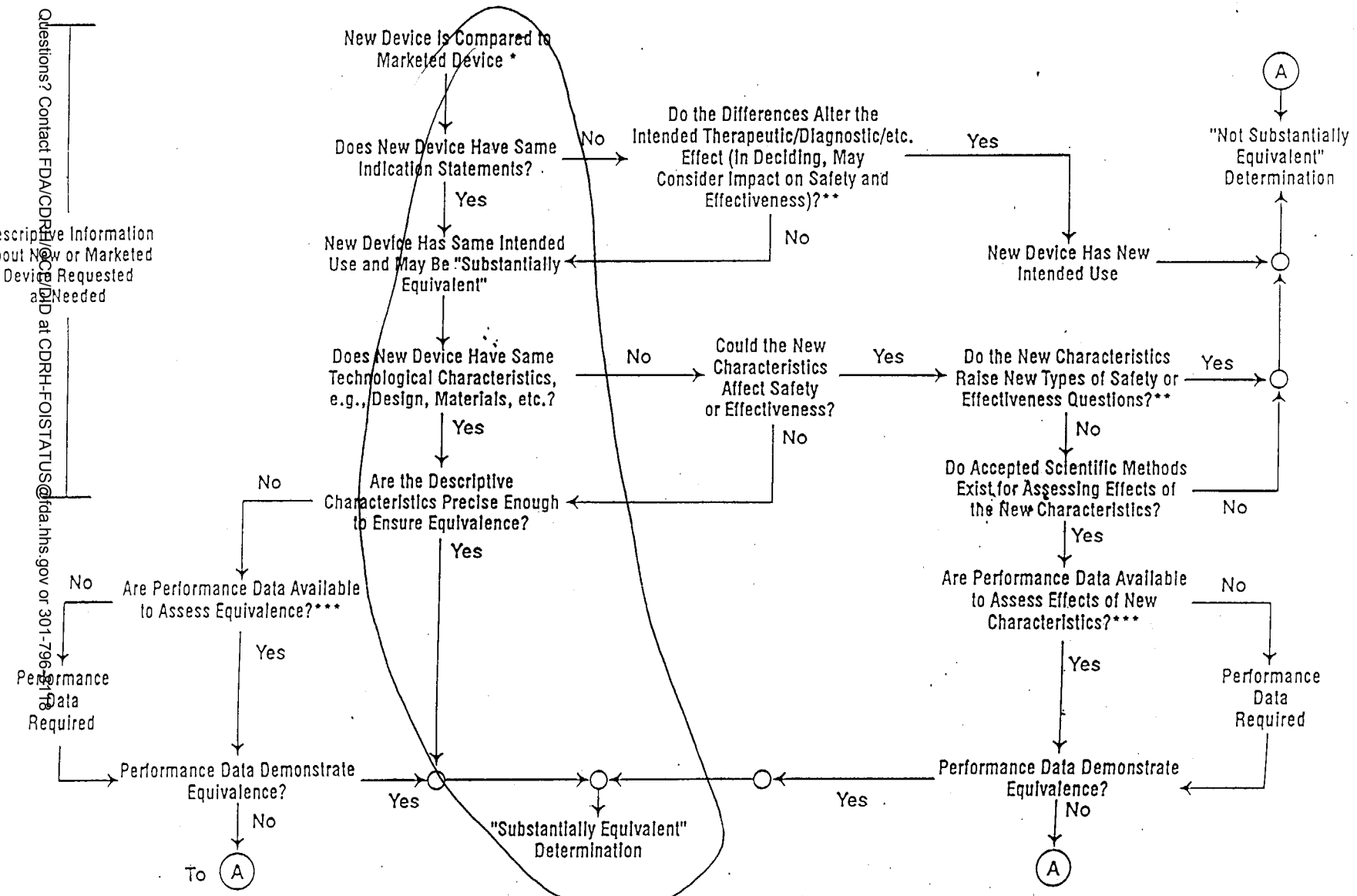
Review: Mark N Melkerson (Branch Chief) ORDB (Branch Code) 3/30/00 (Date)

Final Review: R.P. Ogden for CMW (Division Director) 4/3/2000 (Date)

Revised:8/17//99

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Descriptive Information about New or Marketed Device Requested as Needed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-3118

* 510(k) Submiss[illegible] pare New Devices to Marketed Devices. FDA Requests Additional Inform[illegible] the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is N[illegible] Based on Descriptive Information Alone, But Limited Testing Info[illegible]ion Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		X
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	X X	X
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		X
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		X

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510(K) MEMORANDUM

TO: **K000080**

FROM: Samie Allen, ODE/DGRD/PRSB S. Allen 3/30/00

DATE: March 30, 2000

SUBJ: Stryker Howmedica Osteonics' ASNIS III Cannulated Screw System
Product Code: HWC Classification: 888.3040 Class: II
Product Code: HTN Classification: 888.3030 Class: II

SUMMARY: This 510(k) was originally logged in on 1/11/00; it was reassigned to me on 3/17/00. This 510(k) involves a new nonspinal screw and washer system. It is my recommendation that this 510(k) be found SE.

INTENDED USES/INDICATIONS: In the original submission, the sponsor requested the following uses:

Asnis III 4.0 System
- fractures of the fibula, medial malleolus, os calcis
- fractures of the olecranon, distal humerus
- fractures of the ulna and radius
- patellar fractures
- distal tibia and pion fractures
- fractures of the tarsals and metatarsals
- tarso-metatarsal and metatarso-phalangeal arthrodeses
- metatarsal and phalangeal osteotomies
- *ligament fixation*
- *osteochondritis dissecans*
- *other small fragment, cancellous bone fractures*
- *fractures of the pelvic ring*

Asnis III 5.0mm System
- fixation of intermediate-sized fragments in fractures *such as:*
  - proximal and distal humerus fractures
  - fractures of olecranon process
  - femoral fractures
  - tibial plateau and metaphyseal fractures of the proximal and distal tibia
  - medial and lateral malleolar and pilon fractures
  - os calcis, talar, and patellar fractures
- *ligament fixation of the proximal humerus*
- fractures of the pelvis and acetabulum
- arthrodesis of the tarsals

Asnis III 6.5/8mm System
- intracapsular fractures of the femoral neck
- intertrochanteric fractures of the femur
- tibial plateau fractures
- fractures of the dorsal pelvic ring
- *pelvic sacroiliac joint disruption*
- ankle arthrodesis

On 3/21/00, I discussed the italized indications above w/MXM. MXM did not have an issue with any of them, including the "such as" lead-in to the Asnis 5mm system, with one exception. The indication of "other small fragment, cancellous bone fractures" is too open ended. See deficiency below.

In the 3/29/00 fax, the sponsor replaced the indications above with a more general statement of the Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use." This statement is acceptable.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEVICE DESCRIPTION: The subject system consists of screws and washers.

In the original submission, the sponsor stated that the screws are manufactured from titanium alloy (ASTM F136) or stainless steel (ASTM F138 and DIN 17443 for all diameters or ASTM F1314 for the 6.5 and 8mm diameters). MXM stated that the DIN 17443 is the German standard; I won't ask anything on this because the material does conform to the recognized ASTM F138. However, the sponsor does need to clarify the material versions for each of the screws. Additionally, the sponsor did not state the material for the washers; see deficiency below.

In the 3/29/00 fax, the sponsor provided the following clarification regarding materials:

washers	titanium alloy (ASTM F136) and stainless steel (ASTM F138)
4 and 5mm screws	titanium alloy (ASTM F136) and stainless steel (ASTM F138)
6.5 and 8mm screws	titanium alloy (ASTM F136) and stainless steel (ASTM F138 and ASTM F1314)

These materials apply for both the sterile and nonsterile versions of the device, which rectifies the discrepancy with the original package inserts.

Screws - The screws are available in diameters of 4mm, 5mm, 6.5mm, and 8mm. They are fully or partially threaded. All screws are self-tapping. The subject screws are:

4mm partially threaded screw – 7mm-33.5mm threaded lengths; 14mm-100mm total lengths; 1.55mm cannulation
4mm fully threaded screw – 10mm-100mm lengths
5mm partially threaded screw – 10mm-40mm threaded lengths; 20mm-120mm total lengths; 2.1mm cannulation
5mm fully threaded screw – 16mm-120mm lengths
6.5mm partially threaded screw – 20mm threaded length; 35mm-150mm total lengths; 3.3mm cannulation
6.5mm partially threaded screw – 40mm threaded length; 55mm-150mm total lengths; 3.3mm cannulation
6.5mm fully threaded screw – 20mm-150mm lengths
8mm partially threaded screw – 25mm threaded length; 40mm-150mm total lengths; 3.3mm cannulation
8mm fully threaded screw – 30mm-150mm lengths

Washers – There are 3 standard washers under review. There is one washer for each of the 4mm and 5mm screws, and there is one washer that fits both the 6.5mm and 8mm.

While adequate mechanical drawings were provided for the washers in Appendix A, the sponsor only provided mechanical drawings for 4 of the screws (ti alloy). See deficiency below.

In the 3/29/00 fax, the sponsor stated that the components have the same designs and dimensions regardless of the material they are manufactured from (ASTM F136, F138, or F1314). Therefore, they only provided representative drawings. In the original submission, the sponsor already provided drawings for the partially threaded screws above. In this fax, the sponsor provided drawings to cover the fully threaded screws. This response is adequate.

TESTING: Testing was not provided; however, based on the design of the subject system, none is warranted. This is consistent with ORDB practice regarding these types of devices.

STERILIZATION: The system will be provided both sterile and nonsterile.

Sterile - The system will be sterilized by a minimum of [redacted]g SAL of 10^{-6}. The sterility validation method is ISO/TR 1409. [b]There will be no claims regarding pyrogenicity. A description of the packaging to maintain sterility was provided.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Nonsterile – The recommended set of sterilization is: cycle = (b)(4) [redacted] s. This method was validated for a SAL of 10^{-6}. The sterility validation method is that from AAMI Standards and Recommended Practices, Volume 1: Sterilization.

LABELING:

Label - Adequate sample package labels were provided in Section III of the original submission.

Package insert – In Section III of the original submission, the sponsor provided separate package inserts for the sterile and nonsterile versions of the system. Both need to be revised; see deficiency below.

In the 3/29/00 fax, the sponsor provided revised front pages of each insert. However, this did not address the last part of these deficiencies in which the Warning and Attention regarding pedicle use was to be removed. *In a 3/30/00 email, the sponsor confirmed that the Warning and Attention statements were removed.*

INDICATIONS ENCLOSURE: The original Indications Enclosure needs to be modified; see deficiency below.

In the 3/29/00 fax, the sponsor provided an adequately revised Indications Enclosure.

510(K) SUMMARY: The original 510(k) Summary needs to be modified; see deficiency below.

In the 3/29/00 fax, the sponsor provided an adequately revised 510(k) Summary.

SUBSTANTIAL EQUIVALENCE: The subject screws and washers are SE to numerous previously cleared screws and preamendments screws, in terms of design concept, material, and uses.

510(K) FLOWCHART:

	YES/NO/NA	FLOW
1. Is product a device?	Yes	NO = stop
2. Is device subject to 510k?	Yes	NO = stop
3. Same indication statements?	Yes	YES = go to 5
4. Do differences raise new issues of safety and effectiveness?	N/A	YES = NSE
5. Same technological characteristics?	Yes	YES = go to 7
6. Could the new characteristics effect safety and effectiveness?	N/A	YES = go to 8
7. Descriptive characteristics precise enough?	Yes	NO = go to 10 **YES = SE**
8. New types of safety and effectiveness questions?		YES = NSE
9. Accepted scientific methods exist?		NO = NSE
10. Performance data available?		NO = request data
11. Data demonstrate equivalence?		

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CONTACT RECORD: On 3/21/00, I called Mary-Catherine Dillon and then emailed the following deficiencies. I told her to first fax them so I could look them over before she followed them up by hardcopy.

1. (b)(4)
2.
3.
4.
5.
6.

On 3/30/00, I emailed Mary-Catherine Dillon and asked her about item 6d above.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TOTAL # of PAGES: 13

DATE: March 29, 2000

TO: Samie Allen

FAX: (301) 827-~~4349~~ 4350

FROM: Mary-Catherine Dillon
Howmedica Osteonics

PHONE: (201) 760-8117
FAX: (201) 760-8234

Subject: K000080, Asnis III Cannulated Screw System Deficiency Reponse

Dear Samie,

This fax addresses your deficiencies for the Asnis III Cannulated Screw System. Please let me know if there's anything else you need. Thank you very much for your quick review of this 510(k).

Sincerely,
Mary-Catherine Dillon
Regulatory Affairs, Allendale

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

March 29, 2000

ATTN: Samie Allen
Office of Device Evaluation (510(k))
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Ms. Allen,

Below are the deficiencies you identified for the Asnis III Cannulated Screw System, K000080 and my responses. All responses will initially be provided via fax, and will follow with a hardcopy.

1. (b)(4) [redacted]

We have revised the indications for the Asnis III Cannulated Screw System to read "The Asnis III Cannulated Screw System in intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use."

2. You stated that the screws consist of "titanium alloy (ASTM F136) or stainless steel (ASTM
(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a. (b)(4) [redacted]

b. [redacted]

For clarification, the washers and the 4.0, 5.0, 6.5, and 8.0 diameter screws are available in the following material specifications:

Diameters	Material
All Washers	Titanium (ASTM 136-92) and Stainless Steel (ASTM 138)
4.0 and 5.0	Titanium (ASTM 136-92) and Stainless Steel (ASTM 138)
6.5 and 8.0	Titanium (ASTM 136-92), Stainless Steel (ASTM 138) and Stainless Steel (ASTM 1314)

All subject screws will be manufactured in the materials listed above for both the sterile and non-sterile versions. The package insert for the sterile version of this product will be modified to include ASTM 1314.

3. In Appendix A, you only provided mechanical drawings for some titanium alloy screws and washers. Please provide mechanical drawings for all other titanium screws, as well as all stainless steel screws and washers under review. Make sure that the material versions are consistent with that in your response to item 2a above.

The subject components have the same designs and dimensions regardless of the material they are manufactured from (either ASTM 136-92, ASTM 138, or ASTM 1314). Therefore, the drawings provided are representative of the drawings for all materials. Included in the original submission were the drawings for the partially threaded components. I am now sending you the fully threaded component drawings. This should cover all of the subject components. (Notice that the drawing for the partially threaded 6.5 titanium screw is tabulated, and therefore representative of all 20mm and 40mm thread options.)

4. Please provide a revised Indications Enclosure that reflects your response to item 1 above.

The revised Indications Enclosure is attached.

5. Please provide a revised 510(k) Summary that:
   a. reflects your response to item 1;
   b. clarifies the material issue as per item 2 above; and
   c. adds the following classification for the subject washers – 888.3030, single/multiple component metallic bone fixation appliances and accessories.

The revised 510(k) Summary is attached.

6. Please provide revised nonsterile and sterile package inserts that:
   a. reflects your response to item 1;
   b. clarifies the material issue as per item 2 above;
   c. modifies the lead-in with regards to only having 3 screws as part of the system; and

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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d. removes the Warning (in nonsterile insert) and Attention (in sterile insert) regarding nonpedicle use.

The revised portions of both package inserts are attached.

I hope this response adequately addresses each of your concerns regarding the subject 510(k). Please contact me if you come across further issues. Thank you very much for your quick review of this report.

Mary-Catherine Dillon
Regulatory Affairs

Enclosures:
(4) Drawings
Indications for Use
510(k) Summary
Page 1, Non-Sterile Package Insert
Page 1, Sterile Package Insert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Diagram

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

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510(k) Number (if known): K 000080

Device Name: ASNIS III Cannulated Screw System

Indications For Use:

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
ASNIS III Cannulated Screw System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date Summary Prepared:

December 20, 1999

Device Identification

Proprietary Name:

Asnis III Cannulated Screw System

Common Name:

Cannulated Screws, Washers

Classification Name and Reference:

Smooth of Threaded Metallic Bone Fixation Fastener
21 CFR §888.3040
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
21 CFR §888.3030

Predicate Device Identification

The Asnis III Cannulated Screw System is substantially equivalent to the following marketed devices: Howmedica Asnis II 5.0 and 6.5 Cannulated Screw System, the Synthes 3.5, 4.0, 4.5 and 7.3mm Cannulated Screws, the ACE Medical 4.0, 5.0, 6.5 and 8.0mm Cannulated Screws, the Richards 4.0 Cannulated Screw, the Smith and Nephew 6.5mm Universal Cannulated Screw System and 8.0mm Cannulated Screw System, the AAP 4.0, 4.5, 5.0 and 7.5mm Cannulated Screws , Alphatec 3.5 and 4.0mm Cannulated Screws and Zimmer 4.0 and 5.0mm Cannulated Screws.

Device Description

The Asnis III Cannulated Screw System consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0mm. They are either fully or partially threaded. All screws are

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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selfdrilling and selftapping. There are washers corresponding to the 4.0mm and the 5.0mm screws respectively and one washer fitting for both diameters, 6.5mm and 8.0mm.

Intended Use

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Materials

The subject components can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 and DIN 17443 for all diameters, or ASTM 1314 for the 6.5mm and 8.0mm diameters).

Statement of Technological Comparison

The subject components of the ASNIS III Cannulated Screw System are substantially equivalent in design and intended use to the predicate devices offered by Howmedica Osteonics Corp., Synthes, ACE Medical, Richards, Smith and Nephew, Alphatec, and Zimmer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DRAFT - Package Insert - Sterile Product

OSTEO AG **STERILE PRODUCT**

ASNIS III CANNULATED SCREW SYSTEM

The Asnis III Cannulated Screw System is a fracture fixation system. It is comprised of one washer and four cannulated screws that are intended to provide strong and stable internal fixation with minimal soft tissue irritation. This system is utilized as an aid to healing, not as a substitute for normal intact tissues.

MATERIALS

Titanium alloy (Ti6Al-4V ELI) per ASTM F-136-92	All Screws Washers
Stainless Steel per ASTM 138	All Screws
Stainless Steel per ASTM1314	6.5mm and 8mm Screws

INDICATIONS

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

CONTRAINDICATIONS

Since traumatology products often must be used in emergency situations in order to treat patients with acute injuries, the following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection in or about the affected area.
- Marked local inflammation.
- Any active or suspected latent infection in or about the affected area.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Metal sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant which 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.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Other medical or surgical conditions which would preclude the Potential benefit of surgery, such as the presence of tumors, congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

PRECAUTIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

DRAFT - Package Insert - Non-Sterile Product

OSTEO AG **NON-STERILE PRODUCT**

ASNIS III CANNULATED SCREW SYSTEM

The Asnis III Cannulated Screw System is a fracture fixation system. It is comprised of one washer and four cannulated screws that are intended to provide strong and stable internal fixation with minimal soft tissue irritation. This system is utilized as an aid to healing, not as a substitute for normal intact tissues.

MATERIALS

Titanium alloy (Ti6Al-4V ELI) per ASTM F-136-92	All Screws Washers
Stainless Steel per ASTM 138	All Screws
Stainless Steel per ASTM1314	6.5mm and 8mm Screws

INDICATIONS

The Asnis III Cannulated Screw System is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

CONTRAINDICATIONS

Since traumatology products often must be used in emergency situations in order to treat patients with acute injuries, the following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection in or about the affected area.
- Marked local inflammation.
- Any active or suspected latent infection in or about the affected area.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Metal sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant which 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.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Other medical or surgical conditions which would preclude the Potential benefit of surgery, such as the presence of tumors, congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

PRECAUTIONS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 11, 2000

HOWMEDICA OSTEONICS CORP.
59 ROUTE 17
ALLENDALE, NJ 07401
ATTN: MARY-CATHERINE DILLON

510(k) Number: K000080
Received: 11-JAN-2000
Product: ASNIS III CANNULATED SCREW SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K000080

stryker
Howmedica
OSTEONICS

59 Route 17
Allendale, NJ 07401-1677
Phone: (201) 825-4900
Fax: (201) 934-4369

Via Federal Express

January 10, 2000

Office of Device Evaluation (510(k))
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

FDA/CDRH/ODE/DMC

Attention: Division of Surgical and Rehabilitative Devices

Re: 510(k) Premarket Notification; ASNIS III Cannulated Screw System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) is being submitted prior to the date when Howmedica Osteonics Corp. proposes to introduce into interstate commerce, for commercial distribution, the ASNIS III Cannulated Screw System.

The information submitted herein is in support of the substantial equivalence of the ASNIS III Cannulated Screw System to currently marketed devices. The data is organized in accordance with the following FDA DRAFT guidelines:"Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices, The Basic Elements, April 9, 1993" and "The New 510(k) Paradigm-Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, March 20, 1998".

The Intended Use form for the ASNIS III Cannulated Screw System immediately follows this cover letter. The 510(k) Summary of Safety and Effectiveness, which summarizes the information in the enclosed Premarket Notification, follows the Intended Use form.

NOTICE: This submission contains methods, data, and analysis of these data which Howmedica Osteonics Corp. considers "Trade Secret" and commercially privileged and confidential to Howmedica Osteonics Corp. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act.

DR

II

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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We understand that the submission to the government of false information is prohibited by Title 18 of the United States Code (USC), Part 1001 and Title 21 of the USC, Part 331(q).

To the best of my knowledge, the data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

If there are any questions, or if further information is needed, please contact Ms. Mary-Catherine Dillon, Howmedica Osteonics' Regulatory Affairs Team Member, at (201) 760-8117. Additionally, *please address all related correspondence to Ms. Dillon.*

Sincerely,
Howmedica Osteonics Corp.

Elizabeth A Staub

Elizabeth A. Staub
V.P. - Quality Assurance / Regulatory Affairs / Clinical Research

Enclosures: 510(k) Premarket Notification Application (submitted in duplicate)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Number (if known): K 000080

Device Name: ASNIS III Cannulated Screw System

Revised

Indications For Use:

(b)(4) draft document

[redacted]

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(b)(4) draft document

[redacted]

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
ASNIS III Cannulated Screw System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Team Member

Date Summary Prepared:

December 20, 1999

Device Identification

Proprietary Name:

Asnis III Cannulated Screw System

Common Name:

Cannulated Screws

Classification Name and Reference:

Smooth of Threaded Metallic Bone Fixation Fastener
21 CFR §888.3040

Predicate Device Identification

The Asnis III Cannulated Screw System is substantially equivalent to the following marketed devices: Howmedica Asnis II 5.0 and 6.5 Cannulated Screw System, the Synthes 3.5, 4.0, 4.5 and 7.3mm Cannulated Screws, the ACE Medical 4.0, 5.0, 6.5 and 8.0mm Cannulated Screws, the Richards 4.0 Cannulated Screw, the Smith and Nephew 6.5mm Universal Cannulated Screw System and 8.0mm Cannulated Screw System, the AAP 4.0, 4.5, 5.0 and 7.5mm Cannulated Screws , Alphatec 3.5 and 4.0mm Cannulated Screws and Zimmer 4.0 and 5.0mm Cannulated Screws.

Device Description

The Asnis III Cannulated Screw System consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0mm. They are either fully or partially threaded. All screws are selfdrilling and selftapping. There are washers corresponding to the 4.0mm and the 5.0mm screws respectively and one washer fitting for both diameters, 6.5mm and 8.0mm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use

The Asnis III Cannulated Screw System is indicated for the following:

Asnis III 4.0mm:

Fractures of the fibula, medial malleolus, os calcis
Fractures of the olecranon, distal humerus
Fractures of the ulna and radius
Patellar fractures
Distal tibia and pilon fractures
Fractures of the tarsals and metatarsals
Tarso-metatarsal and metatarso-phalangeal arthrodeses
Metatarsal and phalangeal osteotomies
Ligament fixation
Osteochondritis dissecans
Other small fragment, cancellous bone fractures
Fractures of the pelvic ring

Asnis III 5.0mm:

- Fixation of intermediate-sized fragments in fractures such as:
  - Proximal and distal humerus fractures
  - Fractures of olecranon process
  - Femoral fractures
  - Tibial plateau and metaphyseal fractures of the proximal and distal tibia
  - Medial and lateral malleolar and pilon fractures
  - Os calcis, talar and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodeses of the tarsals

Asnis III 6.5/8.0mm:

Intracapsular fractures of the femoral neck
Intertrochanteric fractures of the femur
Tibial plateau fractures
Fractures of the dorsal pelvic ring
Pelvic sacroiliac joint disruption
Ankle arthrodesis

Materials

The subject components can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 and DIN 17443 for all diameters, or ASTM 1314 for the 6.5mm and 8.0mm diameters).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Statement of Technological Comparison

The subject components of the ASNIS III Cannulated Screw System are substantially equivalent in design and intended use to the predicate devices offered by Howmedica Osteonics Corp., Synthes, ACE Medical, Richards, Smith and Nephew, Alphatec, and Zimmer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) – Premarket Notification
Asnis III Cannulated Screw System

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I

ADMINISTRATIVE INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Manufacturer Identification

Name and Address of the Sponsor* of the 510(k) Submission:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Name and Address of the Manufacturer of the Device:	Osteo AG Bohnackerweg 1 CH-2545 Selzach, Switzerland
Establishment Registration Number:	8043770 (Osteo AG) 2243265 (Howmedica Osteonics Corp.)
Contact Person:	Ms. Mary-Catherine Dillon Regulatory Affairs Team Member Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone (201) 760-8117 Fax (201) 760-8234

- Refer to Appendix C for Osteo AG authorization letter designating Osteonics Corp. (now Howmedica Osteonics Corp.) as its U.S. Designated Agent

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION II

DEVICE IDENTIFICATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Identification

Proprietary Name:	Asnis III Cannulated Screw System
Common Name:	Cannulated Screw
Classification Name and Reference:	Smooth or Threaded Metallic Bone Fixation Fastener 21 CFR §888.3040
Proposed Regulatory Class:	Class II
Device Panel/Product Code:	87 HWC: Screw, Fixation, Bone

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

SECTION III

DEVICE DESCRIPTIVE INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

Introduction

The Asnis III subject components are available in thread diameters of 4.0, 5.0, 6.5, and 8.0 mm. They are either fully or partially threaded. All screws are selfdrilling and selftapping. There are washers corresponding to the 4.0 and the 5.0 screws and one washer fitting for both diameters, 6.5 and 8.0 mm.

The design and function of the Asnis III Cannulated Screw System is substantially equivalent to that of the predicate Osteo Cannulated Screw System in titanium (K971800, K981259 and K983006). Both the subject and predicate systems offer screw thread diameters of 4.0mm, 5.0mm, 6.5mm and 8.0mm, are available in varying lengths, and are either partially or fully threaded. In addition, both the subject and predicate screws can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 and DIN 17443 (for all diameters), or ASTM 1314 (for the 6.5 and 8.0 diameters)). Additionally, the complete Asnis III Cannulated Screw System is available either sterile or non sterile.

Asnis III similarities to other currently marketed devices in terms of materials and dimensions can be found in the comparison tables, pages 10-13. These devices include: Howmedica Asnis II 5.0 and 6.5 Cannulated Screw System, the Synthes 3.5, 4.0, 4.5 and 7.3 mm Cannulated Screw, the ACE Medical 4.0, 5.0, 6.5 and 8.0 mm Cannulated Screw, the Richards 4.0 Cannulated Screw, the Smith and Nephew 6.5mm Universal Cannulated Screw System and 8.0mm Cannulated Screw System, the AAP 4.0, 4.5, 5.0 and 7.5 mm Cannulated Screws , Alphatec 3.5 and 4.0 and Zimmer 4.0 and 5.0 Cannulated Screws. Indications for the Asnis III Cannulated Screw are identical to those of the Asnis II.

Intended Use

The Asnis III Cannulated Screw System is a fracture fixation system, comprised of three washers and four different cannulated screws that are intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. Cannulated screws can help the surgeon to position, determine length, and accurately place the final screw, while maintaining the reduction and control of fracture fragments during surgery. The Asnis III Cannulated Screws may also be used to address tibial plateau fractures and fractures of the dorsal pelvic ring. This system is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Indications

The Asnis III Cannulated Screw System is indicated for the following:

<u>Asnis III 4.0mm:</u>

Fractures of the fibula, medial malleolus, os calcis
Fractures of the olecranon, distal humerus
Fractures of the ulna and radius
Patellar fractures
Distal tibia and pilon fractures
Fractures of the tarsals and metatarsals
Tarso-metatarsal and metatarso-phalangeal arthrodeses
Metatarsal and phalangeal osteotomies
Ligament fixation
Osteochondritis dissecans
Other small fragment, cancellous bone fractures
Fractures of the pelvic ring

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Asnis III 5.0mm:

- Fixation of intermediate-sized fragments in fractures such as:
  - Proximal and distal humerus fractures
  - Fractures of olecranon process
  - Femoral fractures
  - Tibial plateau and metaphyseal fractures of the proximal and distal tibia
  - Medial and lateral malleolar and pilon fractures
  - Os calcis, talar and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodeses of the tarsals

Asnis III 6.5/8.0mm:
Intracapsular fractures of the femoral neck
Intertrochanteric fractures of the femur
Tibial plateau fractures
Fractures of the dorsal pelvic ring
Pelvic sacroiliac joint disruption
Ankle arthrodesis

Contraindications
Since traumatology products often must be used in emergency situations in order to treat patients with acute injuries, the following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection in or about the affected area.
- Marked local inflammation.
- Any active or suspected latent infection in or about the affected area.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Metal sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant which 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.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Other medical or surgical conditions which would preclude the Potential benefit of surgery, such as the presence of tumors, congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

Device Description
The Asnis III Cannulated Screw System consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0 mm. They are either fully or partially threaded. All screws are

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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selfdrilling and selftapping. There are washers corresponding to the 4.0 and the 5.0 screws respectively and one washer fitting for both diameters, 6.5 and 8.0 mm.

For further illustration, please see Appendix A, which contains engineering drawings as well as catalog number designations.

Instrumentation:
The surgical instruments utilized in the operative procedure for the Asnis III Cannulated Screw System are commonly used types of instrumentation for this type of fracture fixation surgery, and as such are Class I manual surgical instruments exempt from 510(k) premarket notification per 21 CFR §888.4540.

Materials
The subject components can be manufactured from either titanium alloy (ASTM 136-92) or stainless steel (ASTM 138 and DIN 17443 for all diameters, or ASTM 1314 for the 6.5 and 8.0 diameters).

Sterility Information
The subject Asnis III Cannulated Screw System components are provided both sterile and non-sterile.

Non-Sterile Components:
All parts must be cleaned and sterilized before use, and are recommended to be sterilized by the following procedure:

- Method: Steam
- Cycle: Wrapped Gravity
- Temperature: 270-F (132'C)
- Exposure Time: 45 Minutes

The recommended sterilization method has been validated, and yields a Sterility Assurance Level (SAL) of 10^{-6}. The sterility validation method utilized to evaluate the recommended sterilization procedure is in accordance with the AAMI Standards and Recommended Practices, Volume 1: Sterilization. (Other sterilization methods and cycles may also be suitable; however, individuals and hospitals are advised to validate whichever method they deem appropriate at their institution.)

Sterile Components:
The following information details the sterilization method used:

- Radiation Type: Gamma radiation
- Radiation Source: (b)(4) [redacted]
- Sterilization Dose:
- Maximum dose:
- Sterility Assurance Level:
- Sterility Validation Method:

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Based Batches." (ISO I-i409:1996(E)

Osteo AG does not make any claims that the sterile devices are "pyrogen-free."

Packaging Information
All packaging will be of sufficient design and material quality to provide protection from physical damage during transportation and storage.

Non-Sterile Packaging:
Typical packaging used for such applications are medical grade peel packs, blister packs, pouches, boxes with foam compartments, clear plastic tubes with end caps and fiberboard shippers and cartons.

Sterile Packaging:
A double blister package is used to maintain the sterility of the subject devices. Each device is placed in an inner blister pack and sealed, and then placed in a second outer blister pack, and sealed again. This combination is then positioned into a cardboard container with foam inserts, and the cardboard container is sealed via the primary package labels.

Labeling
The proposed draft text of the outer package labels and package insert for the subject components (both sterile and non-sterile) of the Asnis III Cannulated Screw System follow.

Clinical Data
Clinical data for the Asnis III Cannulated Screw System is not required in support of this 510(k). The design, materials, and intended use of the subject components are substantially equivalent to those of predicate components.

Substantial Equivalence Information
The Asnis III Cannulated Screw System components are substantially equivalent to other legally marketed Screw System components which are exhibited in Appendix B.

A comparison of the Asnis III Cannulated Screw System components to the predicate devices in terms of materials, design, and size, is presented in the table on the following pages.

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6.5/8.0mm Cannulated Screw Competitive Comparison

Brand	Material	Size Range	Thread Diameter	Thread Length	Self-Drill/ Self-Tap	Reverse Cut Flutes	Shaft	Core	Tip Design	Head	Head Height	Hex Driver	Guide Wire	Cannulation	Washer
ASNIS III 6.5mm	TI-6Al-4V 316L SS 22-13-5	30-120mm 40-130mm	6.5mm	20mm 40mm	Yes	Yes	5.0mm	4.5mm	Tri-fluted	8.0mm Sph. Underside	4.5mm	5.0mm	3.2mm	3.3mm	Yes
ASNIS III 8.0mm	TI-6Al-4V 316L 22-13-5	40-130mm	8.0mm	25mm	Yes	Yes	5.5mm	5.5mm	Tri-fluted Tapered tip	9.0mm Sph. Underside	5.5mm	5.0mm	3.2mm	3.3mm	Yes
ASNIS 2	22-13-5	35-45mm 50-130mm	6.5mm	16mm 20mm	Yes	Yes	4.75mm	5.0mm	Saw-Toothed	8.0mm Sph. Underside	5.0mm	5.75mm	3.2mm	3.3mm	Yes
SYNTHES 7.3mm	316L SS	30-130mm 50-130mm	7.3mm	16mm 32mm	Yes	Yes	4.8mm	4.5mm	Tapered	8.2mm Sph. Underside	4.7mm	4.0mm	2.8mm	2.9mm	Yes
ACE	Ti-6-4	35-120mm	6.5mm	20mm	Yes	No	5.0mm	5.0mm	Saw-Toothed	7.8mm Sph. Underside	5.0mm	5.0mm	3.2mm	3.3mm	Yes
ACE SCFE	Ti-6-4	50-105mm	6.5mm	20mm	Yes	Yes	N/A	N/A	Saw-Toothed	External Hex	N/A	T-Handle Insertion	3.2mm	3.3mm	Yes
BIOMET	Titanium	25-120mm	6.5mm	16mm	Yes	Yes	N/A	N/A	Saw-Toothed	N/A	N/A	5.0mm	3.2mm	3.3mm	Yes
MECRON	316L	N/A	7.0mm	16mm 32mm	No	No	4.9mm	3.8mm	Tapered	9.4mm Sph. Underside	5.5mm	5.5mm	1.7mm	1.8mm	Yes
ORTHOMET	Titanium Alloy	30-125mm	7.5mm	20mm	Yes	Yes	5.5mm	5.5mm	Blunt, Saw-Toothed	Spherical Underside	4.75mm	N/A	3.2mm	3.3mm	Yes

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RICHARDS Universal	316L SS	25+30mm 35-120mm	6.5mm	20mm	No	Yes	4.5mm	4.5mm	Tri-Fluted	8.0mm Sph. Underside	5.0mm	3.5mm	2.4mm	2.5mm	Yes
RICHARDS Hip Pin	316L SS	30-135mm	6.5mm	16mm	No Yes	Yes	4.5mm	4.5mm	Tri-Flanged	Internal Thread External Hex	7.0mm	Insertion Wrench	2.4mm	2.5mm	Yes
RICHARDS 8.0mm	316L SS	50-125mm	8.0mm	16mm	Yes	Yes	5.6mm	5.6mm	Tri-Fluted	Internal Thread External Hex	N/A	Insertion Wrench	3.2mm	3.3mm	Yes
ZIMMER Magna-FX	22-13-5 SS	30-130mm	7.0mm	16mm 32mm	Yes	Yes	5.0mm	5.0mm	Saw-Toothed	7.8mm Sph. Underside	5.0mm	5.0mm	3.2mm	3.3mm	Yes

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Draft Labels

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COMPARISON TABLE

3.5/4.0/5.0mm Cannulated Screw Competitive Comparison

Brand	Material	Size Range	Thread Diameter	Thread Length	Self-Drill/ Self-Tap	Reverse Cut Flutes	Pitch	Shaft	Core	Head Diameter	Hex Driver	Guide Wire	Cannulation	Washer
ASNIS III 4.0mm	Ti 6Al4V 316L SS	10-50mm*; 55-70mm**	4.0mm	min. 10mm or 1/3rd	Yes	Yes	1.75mm	2.5mm	2.5mm	5.0mm	2.5mm	1.4mm	1.55mm	Yes
ASNIS III 5.0mm	Ti 6Al4V 316L SS	20-50mm*; 50-80mm**	5.0mm	1/3 rd	Yes	Yes	2.0mm	3.3mm	3.2mm	6.0mm	3.5mm	2.0mm	2.1mm	Yes
ASNIS 2 4.5/5.0mm	316L SS	20-50* 50-70**; 24-42* 45-70**	4.5mm 5.0mm	Full; Partial	Yes	Yes	0.97mm 1.57mm	3.5mm	3.55mm	8.0mm	3.5mm	2.0mm	2.1mm	Yes
Synthes 3.5mm	316L SS	10-50mm*	3.5mm	Full and Partial	No	Yes	1.25mm	2.5mm	2.5mm	5.0mm	2.5mm	1.25mm	1.35mm	Yes
Synthes 4.0mm	316L SS	10-50mm*	4.0mm	1/2 and 1/3rd	Yes	Yes	1.75mm	2.5mm	2.3mm	5.0mm	2.5mm	1.25mm	1.35mm	Yes
Synthes 4.5mm	316L SS	20-72mm*	4.5mm	Full and Partial	Yes/No	Yes	1.75mm	3.0mm	2.7mm	6.5mm	3.5mm	1.6mm	1.7mm	Yes
ACE 4.0mm	Ti 6Al4V	26-48mm*; 50-70mm***	4.0mm	Partial	Yes	No	N/A	2.6mm	2.8mm	6.2mm	2.5mm	1.6mm	1.65mm	Yes
ACE 5.0mm	Ti 6Al4V	20-70mm*	5.0mm	20mm	Yes	Yes	N/A	N/A	N/A	N/A	N/A	2.0mm	N/A	Yes
Alphatec 3.5mm	Ti 6Al4V	10-30mm*	3.5mm	7mm; 10mm	Yes	No	N/A	2.6mm	2.6mm	N/A	N/A	1.4mm	1.5mm	Yes

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Alphatec 4.0mm	Ti 6Al4V	10-32mm* 40-55mm**	4.0mm	8,12,16mm Partial	Yes	No	N/A	2.9mm	2.9mm	N/A	N/A	1.7mm	1.8mm	Yes
Richards 4.0mm	316L SS	10-30mm* 35-50**	4.0mm	Partial	Yes	No	N/A	2.7mm	2.7mm	6.0mm	3.5mm	1.3mm	1.4mm	Yes
Zimmer Herbert/Whipple	Tivanium	12-30mm*	3.9mm Trailing 3.0mm Leading	3.9mm Trailing 3.0mm Leading	Yes	No	N/A	N/A	N/A	No Screw Head	Hex Recess	1.0mm	1.1mm	Not Required

* 2mm increments ** 5mm increments *** 4mm increments

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REF 326860S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: StSt

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 326660S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: StSt

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 611260S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: Ti6Al4V

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 611060S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: Ti6Al4V

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 326460S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: StSt

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 326060S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: StSt

OSTEO CH-2545 Selzach, Switzerland

V06081

REF 606060S LOT A11111 SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

2004-09

1999-10

STERILE R

CE 0123 Material: Ti6Al4V

OSTEO

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Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

REF 602660S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in Ti
QTY 1
60 mm
2004-09
1999-10
STERILE R
CE 0123 Material: Ti6Al4V
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 325630S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in StSt
QTY 1
30 mm
2004-09
1999-10
STERILE R
CE 0123 Material: StSt
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 325430S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in StSt
QTY 1
30 mm
2004-09
1999-10
STERILE R
CE 0123 Material: StSt
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 601730S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in Ti
QTY 1
30 mm
2004-09
1999-10
STERILE R
CE 0123 Material: Ti6Al4V
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 601630S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in Ti
QTY 1
30 mm
2004-09
1999-10
STERILE R
CE 0123 Material: Ti6Al4V
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 325220S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in StSt
QTY 1
20 mm
2004-09
1999-10
STERILE R
CE 0123 Material: StSt
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 325020S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in StSt
QTY 1
20 mm
2004-09
1999-10
STERILE R
CE 0123 Material: StSt
OSTEO [illegible] Switzerland

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF 604620S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in Ti
QTY 1
20 mm
2004-09
1999-10
STERILE R
CE 0123 Material: Ti6Al4V
OSTEO CH-2545 Selzach, Switzerland
V06081

REF 604620S LOT A11111 SWISS MADE
Asnis III Cannulated Screw in Ti
QTY 1
20 mm
2004-09
1999-10
STERILE R
CE 0123 Material: Ti6Al4V
OSTEO CH-2545 Selzach, Switzerland
V06081

REF390016 Lot A11111 non-sterile SWISS MADE
Washer for Asnis III 6,5 & 8,0
QTY 1
OSTEO CH-2545 Selzach, Switzerland
StSt CE 0123
V06081

REF390017 Lot A11111 non-sterile SWISS MADE
Washer for Asnis III 5.0
QTY 1
OSTEO CH-2545 Selzach, Switzerland
StSt CE 0123
V06081

REF390018 Lot A11111 non-sterile SWISS MADE
Washer for Asnis III 4.0
QTY 1
OSTEO CH-2545 Selzach, Switzerland
StSt CE 0123
V06081

REF619904 Lot A11111 non-sterile SWISS MADE
Washer for Asnis III 6,5 & 8,0
QTY 1
OSTEO CH-2545 Selzach, Switzerland
Ti6Al4V CE 0123
V06081

REF619906 Lot A11111 non-sterile SWISS MADE
Washer for Asnis III 5.0
QTY 1
OSTEO
Ti6Al4V CE 0123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF619905 Lot A11111 non-sterile SWISS MADE

Washer for Asnis III 4.0

QTY 1

OSTEO CH-2545 Selzach, Switzerland Ti6Al4V CE 0123 V06081

REF326860 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland StSt CE 0123 V06081

REF326660 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland StSt CE 0123 V06081

REF611260 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland Ti6Al4V CE 0123 V06081

REF611060 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland Ti6Al4V CE 0123 V06081

REF326460 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland StSt CE 0123 V06081

REF326060 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

60 mm

OSTEO StSt CE 0123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REF606060 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland

Ti6Al4V CE 0123 V06081

REF602660 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

60 mm

OSTEO CH-2545 Selzach, Switzerland

Ti6Al4V CE 0123 V06081

REF325630 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

30 mm

OSTEO CH-2545 Selzach, Switzerland

StSt CE 0123 V06081

REF325430 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

30 mm

OSTEO CH-2545 Selzach, Switzerland

StSt CE 0123 V06081

REF601730 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

30 mm

OSTEO CH-2545 Selzach, Switzerland

Ti6Al4V CE 0123 V06081

REF601630 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

30 mm

OSTEO CH-2545 Selzach, Switzerland

Ti6Al4V CE 0123 V06081

REF325220 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

20 mm

OSTEO

StSt CE 0123

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REF325020 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in StSt

QTY 1

20 mm

StSt CE 0123 V06081

OSTEO CH-2545 Selzach, Switzerland

REF604720 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

20 mm

Ti6Al4V CE 0123 V06081

OSTEO CH-2545 Selzach, Switzerland

REF604620 Lot A11111 non-sterile SWISS MADE

Asnis III Cannulated Screw in Ti

QTY 1

20 mm

Ti6Al4V CE 0123 V06081

OSTEO CH-2545 Selzach, Switzerland

OSTEO CH-2545 Selzach, Switzerland V06081

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Draft Package Inserts

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DRAFT - Package Insert - Non-Sterile Product

OSTEO AG **NON-STERILE PRODUCT**

ASNIS III CANNULATED SCREW SYSTEM

The Asnis III Cannulated Screw System is a fracture fixation system. It is comprised of one washer and three cannulated screws that are intended to provide strong and stable internal fixation with minimal soft tissue irritation. This system is utilized as an aid to healing, not as a substitute for normal intact tissues.

MATERIALS

Titanium alloy (Ti6Al-4V ELI) per ASTM F-136-92	Cannulated Screws, Washer
Stainless Steel per ASTM 138, and ASTM1314	

INDICATIONS

Asnis III 4.0mm:

Fractures of the fibula, medial malleolus, os calcis
Fractures of the olecranon, distal humerus
Fractures of the ulna and radius
Patellar fractures
Distal tibia and pilon fractures
Fractures of the tarsals and metatarsals
Tarso-metatarsal and metatarso-phalangeal arthrodeses
Metatarsal and phalangeal osteotomies
Ligament fixation
Osteochondritis dissecans
Other small fragment, cancellous bone fractures
Fractures of the pelvic ring

Asnis III 5.0mm:

- Fixation of intermediate-sized fragments in fractures such as:
  - Proximal and distal humerus fractures
  - Fractures of olecranon process
  - Femoral fractures
  - Tibial plateau and metaphyseal fractures of the proximal and distal tibia
  - Medial and lateral malleolar and pilon fractures
  - Os calcis, talar and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodeses of the tarsals

Asnis III 6.5/8.0mm:

Intracapsular fractures of the femoral neck
Intertrochanteric fractures of the femur

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Tibial plateau fractures
Fractures of the dorsal pelvic ring
Pelvic sacroiliac joint disruption
Ankle arthrodesis

Contraindications

Since traumatology products often must be used in emergency situations in order to treat patients with acute injuries, the following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection in or about the affected area.
- Marked local inflammation.
- Any active or suspected latent infection in or about the affected area.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Metal sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant which 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.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Other medical or surgical conditions which would preclude the Potential benefit of surgery, such as the presence of tumors, congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

PRECAUTIONS

- Patients who smoke or habitually utilize other forms of nicotine containing products have been shown to have an increase in the incidence of non union. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implants (e.g., substantial walking, running, lifting, or muscle strain), resultant forces can cause failure of the device.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Use of internal fixation systems requires detailed knowledge of the indicated surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such indicated surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful surgical outcome.
- Appropriate selection, placement and fixation of traumatology products are critical factors which affect implant service life. As in the case of all implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants. Accordingly, strict adherence to the indications,

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contraindications, precautions and warnings for this product is essential to potentially maximize service life.

- Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen, or fracture if excessive demands are placed on it. An active, debilitated, or psychologically compromised patient who cannot properly use weight support devices may be particularly at risk during postoperative rehabilitation. A successful result is not achieved in every surgical case.
- Care must be taken to protect the implants from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in the device and internal stresses which may become the focal point for eventual breakage of the implant.
- All Osteo Instruments may be required for each surgery. Failure to use dedicated instruments for every step of the implantation technique may compromise the integrity of the implanted device leading to premature device failure and subsequent patient injury.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
- Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

UTILIZATION AND IMPLANTATION

- Use of internal fixation systems requires detailed knowledge of orthopedic fixation surgery. This device is recommended for use only by surgeons familiar with the surgical techniques, cautions, and potential risks associated with orthopedic fixation surgery. Any surgeon who is not familiar with the associated surgery should consult the available medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with the procedure.
- Postoperative Mobilization: Prior to adequate fracture consolidation, implanted fixation devices alone cannot provide sufficient strength to accommodate full loaded bearing without external support. External immobilization by bracing or casting may be employed from two to four months postoperatively or until x-rays or other procedures confirm adequate fracture healing.
- The applicable surgical protocol provides additional information and should be read and fully understood prior to use of the device.

WARNINGS

- Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until consolidation is confirmed, do not subject this device to excessive motion, or implant failure may result.
- Discard all damaged or mishandled implants.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- Never reuse an implant, even though it may appear undamaged.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load. For those products which Osteo prescribes contouring or bending, such action must be performed with Osteo instruments and in stages in accordance with Osteo's specified procedures. Use of unsuitable instruments or excessive manipulation may lead to premature or eventual compromise of the implant.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Mixing metals: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices which come into contact with other metal objects must be made from like or compatible metals.
- Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the Osteo system should not be used in conjunction with components from any other manufacturer's system. Osteo strongly advises against the use of another manufacturer's bone screws with any Osteo system component, due to variations which exist between screw head and screw seat configurations. Any such use will negate the responsibility of Osteo for the performance of the resulting mixed component implant.
- No implant can withstand body loads without supportive bone. In this event, bending, fraying, kinking, loosening, disassembly and/or breakage of the device(s) will eventually occur. Reoperation to remove or replace implants may be required at any time due to medical or device related reasons. If corrective action is not taken, complications may occur. These complications may include but are not limited to:
    - Corrosion with localized tissue reaction and pain;
    - Migration of implant position resulting in injury;
    - Risk of additional injury from postoperative trauma;
    - Bending, loosening, and/or breakage, which could make removal impractical or difficult;
    - Pain, discomfort, or abnormal sensations due to the presence of the device;
    - Possible increased risk of infection; and,
    - Bone loss due to stress shielding.
- Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
- Bone formation around the implant may make removal of the implant difficult or impossible
- Prevent implants from contact with any foreign material and fluid media which may infiltrate and permanently contaminate the implants.

ADVERSE EFFECTS

- While the expected life of implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of bone and reduction of pain. However, due to the many

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biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

- Bending, disassembly or fracture of any or all implant components.
- Loosening of the implant can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of implants has occurred in a small percentage of cases. Implant fracture is more likely to occur in the heavy, physically active individual or may result due to inadequate support of the implant by the underlying bone or poor component fixation.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunited fracture results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Peripheral neuropathies, nerve damage, circulatory compromise, superficial or deep infection, bursitis and/or heterotopic bone formation may occur.
- Serious complications may be associated with any trauma-related surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of trauma implants has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Intraoperative fissure, fracture, or perforation of the bone can occur due to numerous factors including the presence of defects, poor bone stock, the use of the surgical instruments and the implantation of the implant into the surgical site.
- Decrease in bone density due to stress shielding.
- Pain may occur due to loosening of the implant.
- If bone screws are used, appropriate selection of bone screw length and location is essential to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Pressure on skin from components where inadequate tissue coverage exists over the implants, with potential extrusion through the skin.
- Metal sensitivity reactions have been reported following fracture fixation.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

STERILIZATION

- This device is **not** sterile.

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- Remove all devices from their packaging prior to sterilization.
- All parts must be cleaned and sterilized before use. Cleaning should be performed manually, ultrasonically, and in accordance with the specifications designated by the manufacturer of the hospital's equipment.
- Osteo's implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital. The suggested method is based on HIMA and AORN recommended practices and consists of the following:

Method:	Steam
Cycle:	Wrapped Gravity
Temperature:	270° F (132° C)
Exposure Time:	45 minutes

  The above recommended sterilization cycle has been validated. Other sterilization methods and cycles may also be suitable. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
- EtO sterilization and cold sterilization techniques are not recommended.

WARNING: Osteo Bone Screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

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DRAFT - Package Insert - Sterile Product

OSTEO AG **STERILE PRODUCT**

ASNIS III CANNULATED SCREW SYSTEM

The Asnis III Cannulated Screw System is a fracture fixation system. It is comprised of one washer and three cannulated screws that are intended to provide strong and stable internal fixation with minimal soft tissue irritation. This system is utilized as an aid to healing, not as a substitute for normal intact tissues.

MATERIALS

Titanium alloy (Ti6Al-4V ELI) per ASTM F-136-92	Cannulated Screws, Washer

INDICATIONS

Asnis III 4.0mm:
Fractures of the fibula, medial malleolus, os calcis
Fractures of the olecranon, distal humerus
Fractures of the ulna and radius
Patellar fractures
Distal tibia and pilon fractures
Fractures of the tarsals and metatarsals
Tarso-metatarsal and metatarso-phalangeal arthrodeses
Metatarsal and phalangeal osteotomies
Ligament fixation
Osteochondritis dissecans
Other small fragment, cancellous bone fractures
Fractures of the pelvic ring

Asnis III 5.0mm:

- Fixation of intermediate-sized fragments in fractures such as:
  - Proximal and distal humerus fractures
  - Fractures of olecranon process
  - Femoral fractures
  - Tibial plateau and metaphyseal fractures of the proximal and distal tibia
  - Medial and lateral malleolar and pilon fractures
  - Os calcis, talar and patellar fractures
- Ligament fixation of the proximal humerus
- Fractures of the pelvis and acetabulum
- Arthrodeses of the tarsals

Asnis III 6.5/8.0mm:
Intracapsular fractures of the femoral neck
Intertrochanteric fractures of the femur

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Tibial plateau fractures
Fractures of the dorsal pelvic ring
Pelvic sacroiliac joint disruption
Ankle arthrodesis

Contraindications

Since traumatology products often must be used in emergency situations in order to treat patients with acute injuries, the following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection in or about the affected area.
- Marked local inflammation.
- Any active or suspected latent infection in or about the affected area.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the devices.
- Metal sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant which 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.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Other medical or surgical conditions which would preclude the Potential benefit of surgery, such as the presence of tumors, congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count.

PRECAUTIONS

- Patients who smoke or habitually utilize other forms of nicotine containing products have been shown to have an increase in the incidence of non union. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implants (e.g., substantial walking, running, lifting, or muscle strain), resultant forces can cause failure of the device.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Use of internal fixation systems requires detailed knowledge of the indicated surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such indicated surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful surgical outcome.
- Appropriate selection, placement and fixation of traumatology products are critical factors which affect implant service life. As in the case of all implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants. Accordingly, strict adherence to the indications,

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contraindications, precautions and warnings for this product is essential to potentially maximize service life.

- Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen, or fracture if excessive demands are placed on it. An active, debilitated, or psychologically compromised patient who cannot properly use weight support devices may be particularly at risk during postoperative rehabilitation. A successful result is not achieved in every surgical case.
- Care must be taken to protect the implants from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in the device and internal stresses which may become the focal point for eventual breakage of the implant.
- All Osteo Instruments may be required for each surgery. Failure to use dedicated instruments for every step of the implantation technique may compromise the integrity of the implanted device leading to premature device failure and subsequent patient injury.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
- Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

UTILIZATION AND IMPLANTATION

- Use of internal fixation systems requires detailed knowledge of orthopedic fixation surgery. This device is recommended for use only by surgeons familiar with the surgical techniques, cautions, and potential risks associated with orthopedic fixation surgery. Any surgeon who is not familiar with the associated surgery should consult the available medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with the procedure.
- Postoperative Mobilization: Prior to adequate fracture consolidation, implanted fixation devices alone cannot provide sufficient strength to accommodate full loaded bearing without external support. External immobilization by bracing or casting may be employed from two to four months postoperatively or until x-rays or other procedures confirm adequate fracture healing.
- The applicable surgical protocol provides additional information and should be read and fully understood prior to use of the device.

WARNINGS

- Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until consolidation is confirmed, do not subject this device to excessive motion, or implant failure may result.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

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- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load. For those products which Osteo prescribes contouring or bending, such action must be performed with Osteo instruments and in stages in accordance with Osteo's specified procedures. Use of unsuitable instruments or excessive manipulation may lead to premature or eventual compromise of the implant.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Mixing metals: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices which come into contact with other metal objects must be made from like or compatible metals.
- Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the Osteo system should not be used in conjunction with components from any other manufacturer's system. Osteo strongly advises against the use of another manufacturer's bone screws with any Osteo system component, due to variations which exist between screw head and screw seat configurations. Any such use will negate the responsibility of Osteo for the performance of the resulting mixed component implant.
- No implant can withstand body loads without supportive bone. In this event, bending, fraying, kinking, loosening, disassembly and/or breakage of the device(s) will eventually occur. Reoperation to remove or replace implants may be required at any time due to medical or device related reasons. If corrective action is not taken, complications may occur. These complications may include but are not limited to:
    - Corrosion with localized tissue reaction and pain;
    - Migration of implant position resulting in injury;
    - Risk of additional injury from postoperative trauma;
    - Bending, loosening, and/or breakage, which could make removal impractical or difficult;
    - Pain, discomfort, or abnormal sensations due to the presence of the device;
    - Possible increased risk of infection; and,
    - Bone loss due to stress shielding.
- Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
- Bone formation around the implant may make removal of the implant difficult or impossible
- Prevent implants from contact with any foreign material and fluid media which may infiltrate and permanently contaminate the implants.

ADVERSE EFFECTS

- While the expected life of implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of bone and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but

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cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

- Bending, disassembly or fracture of any or all implant components.
- Loosening of the implant can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of implants has occurred in a small percentage of cases. Implant fracture is more likely to occur in the heavy, physically active individual or may result due to inadequate support of the implant by the underlying bone or poor component fixation.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunited fracture results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Peripheral neuropathies, nerve damage, circulatory compromise, superficial or deep infection, bursitis and/or heterotopic bone formation may occur.
- Serious complications may be associated with any trauma-related surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of trauma implants has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Intraoperative fissure, fracture, or perforation of the bone can occur due to numerous factors including the presence of defects, poor bone stock, the use of the surgical instruments and the implantation of the implant into the surgical site.
- Decrease in bone density due to stress shielding.
- Pain may occur due to loosening of the implant.
- If bone screws are used, appropriate selection of bone screw length and location is essential to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Pressure on skin from components where inadequate tissue coverage exists over the implants, with potential extrusion through the skin.
- Metal sensitivity reactions have been reported following fracture fixation.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

STERILIZATION

- This component has been sterilized by gamma radiation.

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- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed non-sterile.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product may be resterilized by the steam autoclaving procedure regularly used in the hospital. The suggested method is based on HIMA and AORN recommended practices and consists of the following:

Method:	Steam
Cycle:	Wrapped Gravity
Temperature:	270° F (132° C)
Exposure Time:	45 minutes

The above recommended sterilization cycle has been validated. Other sterilization methods and cycles may also be suitable. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques. EtO sterilization and cold sterilization techniques are not recommended.

ATTENTION: Osteo Bone Screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDICES

APPENDIX A	Device Information
A-1	Engineering Drawings
A-2	Catalog Number Designations
APPENDIX B	Predicate Devices in Commercial Distribution
APPENDIX C	Osteo AG Authorization Letter
APPENDIX D	Chapters 7 and 15 from Cannulated Screw Fixation: Principles and Operative Techniques

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APPENDIX A

Device Information

A-1	Engineering Drawings
A-2	Catalog Number Designations

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APPENDIX A-1

Engineering Drawings

- CONFIDENTIAL -

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(b)(4) Engineering Drawings

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APPENDIX A-2

Catalog Number Designations

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APPENDIX A-2
CATALOG NUMBER DESIGNATIONS

ASNIS III Cannulated Screws ø4.0 mm in Ti

Screw Length	Titanium	
	Partial Thread	Full Thread
10mm		604710
12mm		604712
14mm	604614	604714
16mm	604616	604716
18mm	604618	604718
20mm	604620	604720
22mm	604622	604722
24mm	604624	604724
26mm	604626	604726
28mm	604628	604728
30mm	604630	604730
32mm	604632	604732
34mm	604634	604734
36mm	604636	604736
38mm	604638	604738
40mm	604640	604740
42mm	604642	604742
44mm	604644	604744
46mm	604646	604746
48mm	604648	604748
50mm	604650	604750
55mm	604655	604755
60mm	604660	604760
65mm	604665	604765
70mm	604670	604770
75mm	604675	604775
80mm	604680	604780
85mm	604685	604785
90mm	604690	604790
95mm	604695	604795
100mm	604700	604800

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ASNIS III Cannulated Screws ø4.0 mm in StSt

Screw Length	Steel	
	Partial Thread	Full Thread
10mm		325210
12mm		325212
14mm	325014	325214
16mm	325016	325216
18mm	325018	325218
20mm	325020	325220
22mm	325022	325222
24mm	325024	325224
26mm	325026	325226
28mm	325028	325228
30mm	325030	325230
32mm	325032	325232
34mm	325034	325234
36mm	325036	325236
38mm	325038	325238
40mm	325040	325240
42mm	325042	325242
44mm	325044	325244
46mm	325046	325246
48mm	325048	325248
50mm	325050	325250
55mm	325055	325255
60mm	325060	325260
65mm	325065	325265
70mm	325070	325270
75mm	325075	325275
80mm	325080	325280
85mm	325085	325285
90mm	325090	325290
95mm	325095	325295
100mm	325100	325300

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ASNIS III Cannulated Screws ø5.0 mm in Ti

Screw Length	Titanium	
	Partial Thread	Full Thread
16mm		601716
18mm		601718
20mm	601620	601720
22mm	601622	601722
24mm	601624	601724
26mm	601626	601726
28mm	601628	601728
30mm	601630	601730
32mm	601632	601732
34mm	601634	601734
36mm	601636	601736
38mm	601638	601738
40mm	601640	601740
42mm	601642	601742
44mm	601644	601744
46mm	601646	601746
48mm	601648	601748
50mm	601650	601750
55mm	601655	601755
60mm	601660	601760
65mm	601665	601765
70mm	601670	601770
75mm	601675	601775
80mm	601680	601780
85mm	601685	601785
90mm	601690	601790
95mm	601695	601795
100mm	601700	601800
105mm	601705	601805
110mm	601710	601810
115mm	601715	601815
120mm	601720	601820

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ASNIS III Cannulated Screws ø5.0 mm in StSt

Screw Length	Steel	
	Partial Thread	Full Thread
16mm		325616
18mm		325618
20mm	325420	325620
22mm	325422	325622
24mm	325424	325624
26mm	325426	325626
28mm	325428	325628
30mm	325430	325630
32mm	325432	325632
34mm	325434	325634
36mm	325436	325636
38mm	325438	325638
40mm	325440	325640
42mm	325442	325642
44mm	325444	325644
46mm	325446	325646
48mm	325448	325648
50mm	325450	325650
55mm	325455	325655
60mm	325460	325660
65mm	325465	325665
70mm	325470	325670
75mm	325475	325675
80mm	325480	325680
85mm	325485	325685
90mm	325490	325690
95mm	325495	325695
100mm	325500	325700
105mm	325505	325705
110mm	325510	325710
115mm	325515	325715
120mm	325520	325720

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ASNIS III Cannulated Screws ø6.5 mm in Ti

Screw Length	Titanium		
	20mm Thread	40mm Thread	Full Thread
20mm			606020
25mm			606025
30mm			606030
35mm	602635		606035
40mm	602640		606040
45mm	602645		606045
50mm	602650		606050
55mm	602655	602855	606055
60mm	602660	602860	606060
65mm	602665	602865	606065
70mm	602670	602870	606070
75mm	602675	602875	606075
80mm	602680	602880	606080
85mm	602685	602885	606085
90mm	602690	602890	606090
95mm	602695	602895	606095
100mm	602700	602900	606100
105mm	602705	602905	606105
110mm	602710	602910	606110
115mm	602715	602915	606115
120mm	602720	602920	606120
125mm	602725	602925	606125
130mm	602730	602930	606130
135mm	602735	602935	606135
140mm	602740	602940	606140
145mm	602745	602945	606145
150mm	602750	602950	606150

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ASNIS III Cannulated Screws ø6.5 mm in StSt

Screw Length	Steel		
	20mm Thread	40mm Thread	Full Thread
20mm			326420
25mm			326425
30mm			326430
35mm	326035		326435
40mm	326040		326440
45mm	326045		326445
50mm	326050		326450
55mm	326055	326255	326455
60mm	326060	326260	326460
65mm	326065	326265	326465
70mm	326070	326270	326470
75mm	326075	326275	326475
80mm	326080	326280	326480
85mm	326085	326285	326485
90mm	326090	326290	326490
95mm	326095	326295	326495
100mm	326100	326300	326500
105mm	326105	326305	326505
110mm	326110	326310	326510
115mm	326115	326315	326515
120mm	326120	326320	326520
125mm	326125	326325	326525
130mm	326130	326330	326530
135mm	326135	326335	326535
140mm	326140	326340	326540
145mm	326145	326345	326545
150mm	326150	326350	326550

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ASNIS III Cannulated Screws ø8.0 mm in Ti

Screw Length	Titanium	
	Partial Thread	Full Thread
30mm		611230
35mm		611235
40mm	611040	611240
45mm	611045	611245
50mm	611050	611250
55mm	611055	611255
60mm	611060	611260
65mm	611065	611265
70mm	611070	611270
75mm	611075	611275
80mm	611080	611280
85mm	611085	611285
90mm	611090	611290
95mm	611095	611295
100mm	611100	611300
105mm	611105	611305
110mm	611110	611310
115mm	611115	611315
120mm	611120	611320
125mm	611125	611325
130mm	611130	611330
135mm	611135	611335
140mm	611140	611340
145mm	611145	611345
150mm	611150	611350

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ASNIS III Cannulated Screws ø8.0 mm in StSt

Screw Length	Steel	
	Partial Thread	Full Thread
30mm		326830
35mm		326835
40mm	326640	326840
45mm	326645	326845
50mm	326650	326850
55mm	326655	326855
60mm	326660	326860
65mm	326665	326865
70mm	326670	326870
75mm	326675	326875
80mm	326680	326880
85mm	326685	326885
90mm	326690	326890
95mm	326695	326895
100mm	326700	326900
105mm	326705	326905
110mm	326710	326910
115mm	326715	326915
120mm	326720	326920
125mm	326725	326925
130mm	326730	326930
135mm	326735	326935
140mm	326740	326940
145mm	326745	326945
150mm	326750	326950

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX B

Predicate Devices in Commercial Distribution

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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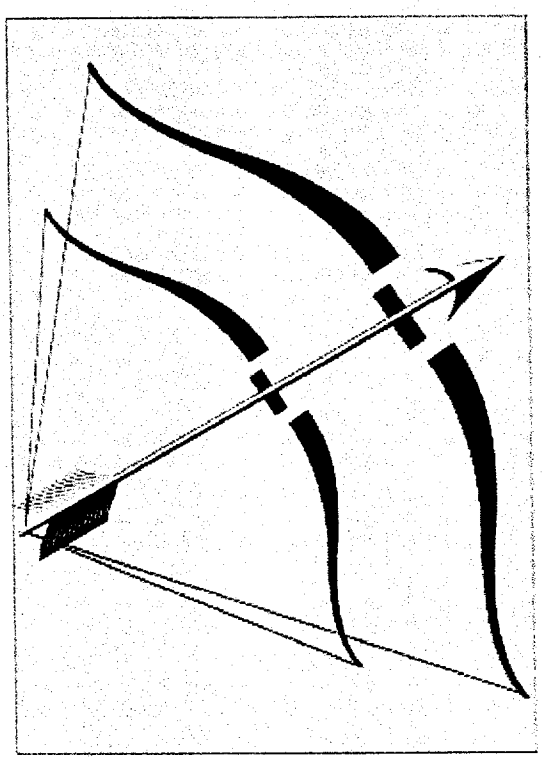
ASNIS 2
SMALLØ
CANNULATED SCREW SYSTEM



Another String to Your Bow

Howmedica®

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ASNIS 2
SMALLØ
GUIDED SCREW SYSTEM

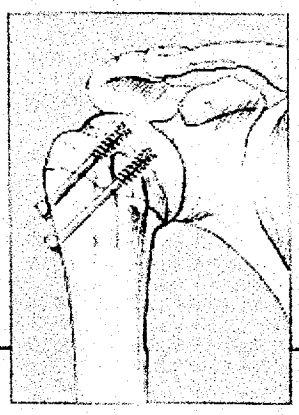
Now, for Additional Surgical Applications

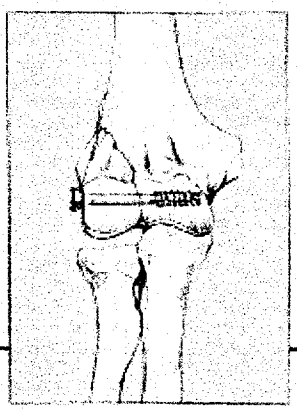
Expanding on the Original and Best Technology

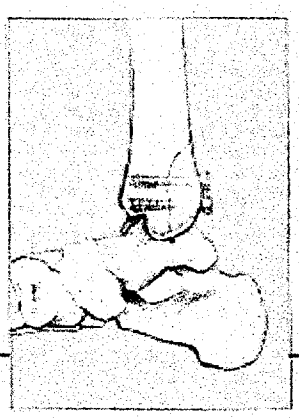
Howmedica revolutionized fracture management with the introduction of the original Asnis Guided Screw System. Now, the evolution continues with the introduction of the Asnis 2 Small Diameter Guided Screw System, expanding this unique fracture management concept to a broader range of surgical applications.

New 4.5mm diameter fully threaded cortical and 5.0mm diameter partially threaded cancellous Asnis 2 Screws are available for fractures of the wrist, ankle, shoulder, pelvis, elbow, condyles of long bones, and diaphyseal fractures of long bones.

All Asnis 2 Guided Screws can be used alone or with plates, and are packaged sterile for easy handling and immediate use.







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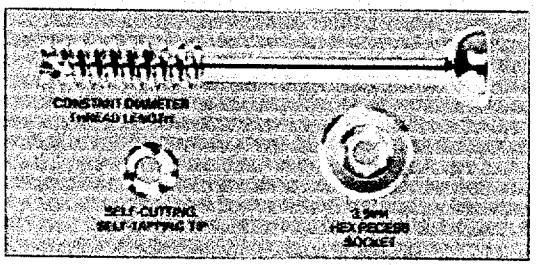
Proven Asnis 2 Cutting Technology

The dynamic cutting tip of the Asnis 2 Small Diameter Screw is the same proven design as in the larger diameter Asnis 2 Screw, facilitating easy introduction and placement without pre-drilling or pre-tapping in most cases.

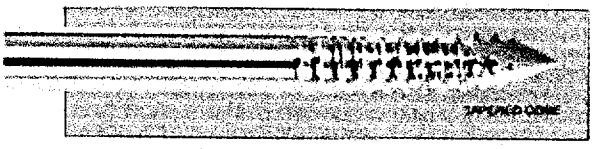
Constant diameter thread length to the tip of the screw provides optimal purchase as compared to tapered-tip screws. Optimal thread pitch provides greater resistance to pull-out.

Reverse cutting flutes facilitate screw removal in hard bone.



Unique Guide Pin Design

The Asnis 2 System features a threaded Guide Pin* with a tapered core to reduce the potential for a stress riser at the thread/shank junction. The threaded tip provides secure purchase while the cannulated screw is guided into its correct position



Standard Head Design

Small Diameter Asnis 2 Screws, manufactured from 316 LVM stainless steel, incorporate such proven features as 8.0mm diameter heads with standard 3.5mm hex recess socket drives, and conform to most stainless steel bone plates.

Simple Surgical Technique

The Asnis 2 Small Diameter Guided Screw System makes screw placement as easy as 1-2-3.

Step 1: Guide Pin placement with the aid of the Pin Guide.

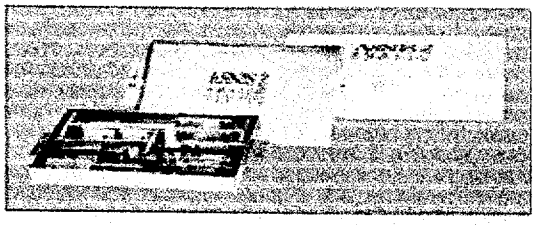
Step 2: Depth measurement, using the easy-to-read Pin Depth Gauge.

Step 3: Placement of the self-cutting, self-tapping cannulated screw directly over the Guide Pin.

The Asnis 2 Pin Guide permits introduction of an additional Guide Pin to aid in reduction and/or provide rotational control.

Simple Instrumentation

The Asnis 2 Small Diameter Guided Screw System features lightweight, easy-to-handle instruments, and an innovative case-within-a-case that reduces clutter in the operating room. The instrument case can be used alone. However, if the need is to present all Asnis 2 Screws in the operating theatre, the instrument case can be placed inside the separate screw case (sold separately).



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Catalogue Information

Implants

Asnis 2 Guided Screws 4.0mm Cannulated (Fully Threaded) 3.5mm Hex Head	
Cat. No	Length mm
3550-3-020	20
3550-3-022	22
3550-3-024	24
3550-3-026	26
3550-3-028	28
3550-3-030	30
3550-3-032	32
3550-3-034	34
3550-3-036	36
3550-3-038	38
3550-3-040	40
3550-3-042	42
3550-3-045	45
3550-3-050	50
3550-3-055	55
3550-3-060	60
3550-3-065	65
3550-3-070	70

Asnis 2 Guided Screws 5.0mm Cannulated (Partially Threaded) 3.5mm Hex Head	
Cat. No	Length mm
3550-4-024	[illegible]
3550-4-026	26
3550-4-028	28
3550-4-030	30
3550-4-032	32
3550-4-034	34
3550-4-036	36
3550-4-038	38
3550-4-040	40
3550-4-042	42
3550-4-045	45
3550-4-050	50
3550-4-055	55
3550-4-060	60
3550-4-065	65
3550-4-070	70

Instrumentation

3550-2-030
2.0mm x 150mm Guide Pin

3550-2-040
Pin Depth Gauge 20mm to 70mm

3550-6-045
2.6mm x 150mm Step Bone Drill

3550-3-080
Washers

3550-2-300
Cannulated Screwdriver

3550-2-270
Cannulated Chamfer

3550-2-310
Cannulated Inner Shaft

3781-0-023
2.0mm Pin Guide

3550-2-320
4.0mm Cannulated Cutting Tip

3550-2-325
Sleeve

3550-2-330
5.0mm Cannulated Cutting Tip

3550-4-100
Instrument Case

3550-2-340
Cannulated Countersink

3550-4-200
Screw Case

Howmedica

TRAUMA

solutions

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*Patent Applied for.

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A504/0092-5E

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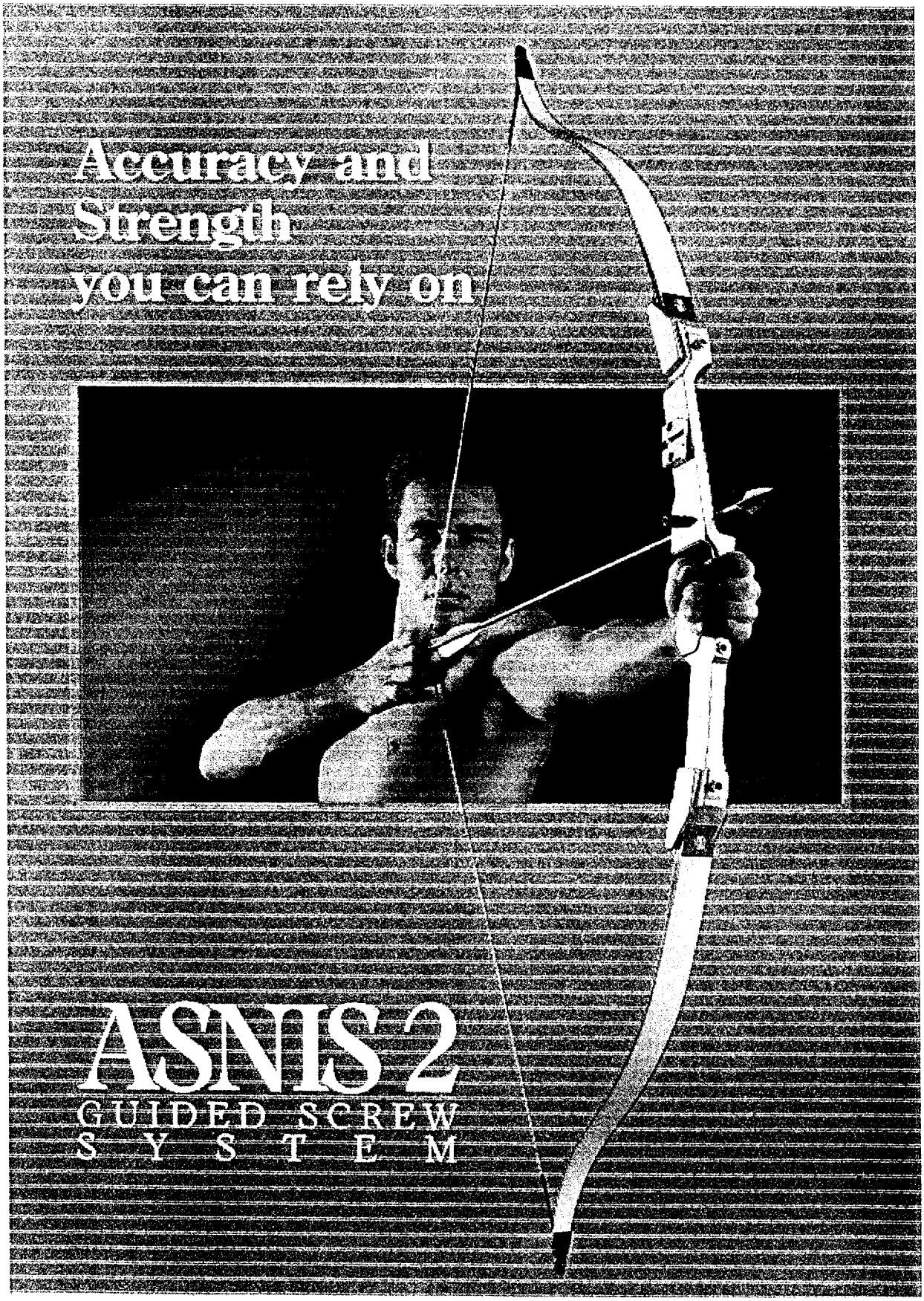

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ASNIS 2

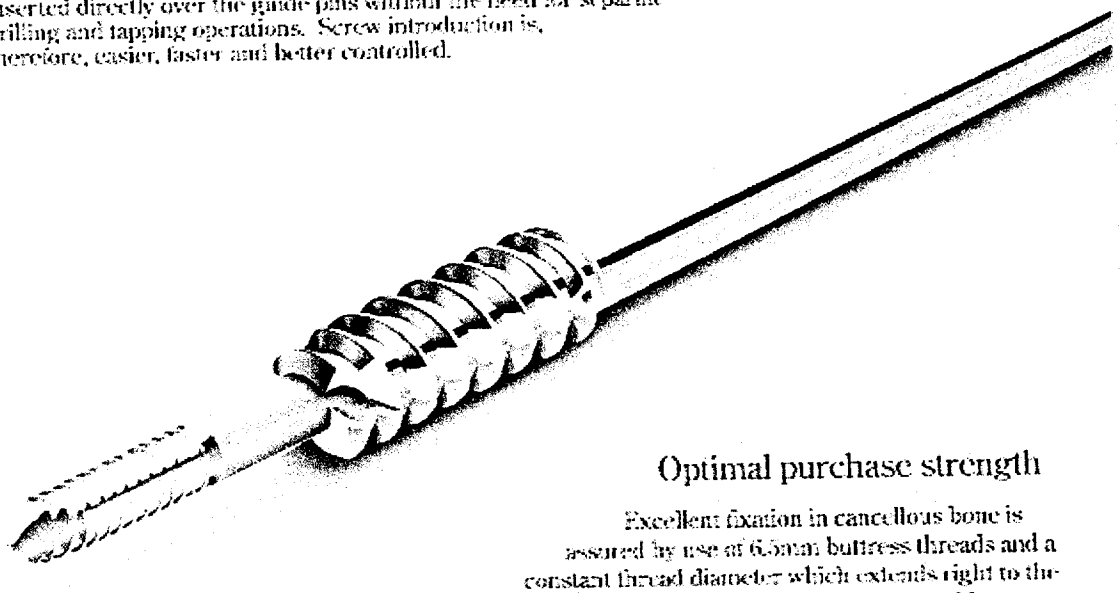
A new generation of cannulated screws

Strength of material and design

The ASNIS 2 Screw is constructed of 22-13-5 Stainless Steel Alloy, one of the strongest materials available for fracture fixation.

A unique cutting tip for ease of introduction and precise placement

The ASNIS 2 Screw has a unique self-cutting, self-tapping tip which enables screws to be inserted directly over the guide pins without the need for separate drilling and tapping operations. Screw introduction is, therefore, easier, faster and better controlled.



Optimal purchase strength

Excellent fixation in cancellous bone is assured by use of 6.0mm buttress threads and a constant thread diameter which extends right to the tip. In addition, the 20mm thread length provides an optimal number of threads for any application with highly effective pullout resistance.

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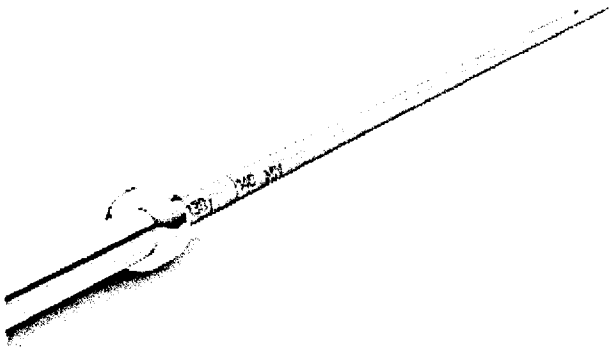
for strong and stable fracture fixation



Easy removal

Reverse cutting flutes facilitate removal in harder bone such as that seen in a young patient with a slipped femoral epiphysis. The risk of screw breakage on removal is minimised because, in addition to its super-strong construction, the root diameter of the screw thread is the same as the shank, thus ensuring stress concentrations at the junction of the thread and shaft are reduced.

Accuracy with simplicity in fracture fixation

Stainless Steel Alloy 22-13-5 allows the use of a Guided Screw with a large cannulation which, in turn, allows a large diameter (3.2mm) guide pin to be placed directly across the fracture site with little risk of deflection. The resulting accurate placement of guide pins ensures the parallel positioning of Asnis 2 screws within the femoral head.

Choice of pin guide

Two specially designed Fixed Pin Guides assist in correct Pin positioning in patterns which yield excellent rotational stability and help protect against loss of position of the femoral head into varus or posterior angulation when the patient stands or gets up from a sitting position.

Direct selection of screw size

Laser-etched graduated markings on the unique satin surface finish of the Guide Pin allow *direct* measurement of screw size without the need for a separate depth gauge.

Straightforward procedure

Despite these refinements, the ASNIS 2 Guided Screw System involves the use of relatively few instruments, many of which are optional not mandatory, and is extremely simple to use...

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ASNIS 2

Simple 2-step surgical technique -

- **Easy insertion:**
  due to unique, self-cutting, self-tapping tip.

- **Optimal accuracy:**
  Super strong, large diameter Guide Pins and specially designed Pin Guides ensure optimal accuracy for parallel screw placement.

- **Simple procedure:**
  Two step technique that is quick and easy to perform with minimised patient trauma.

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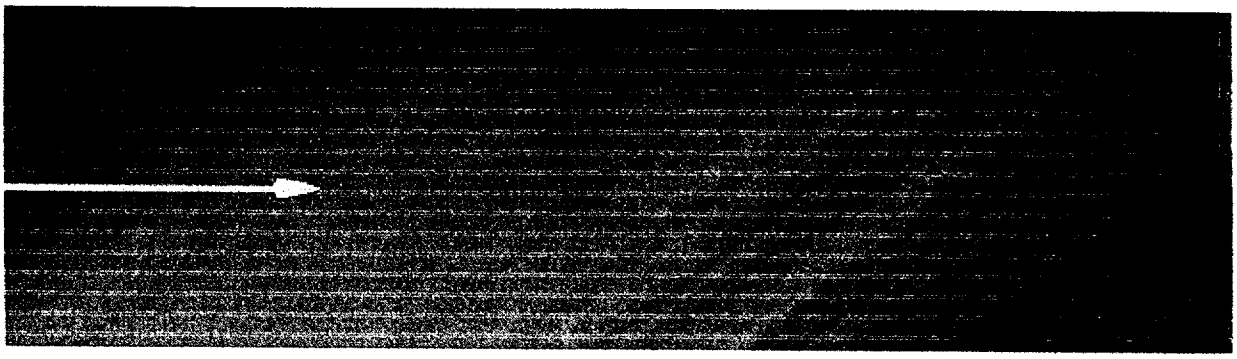
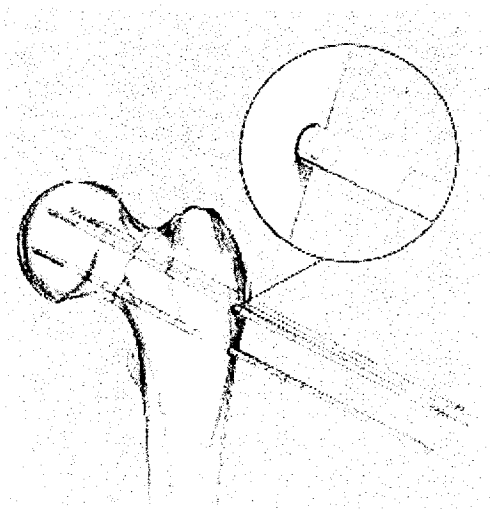


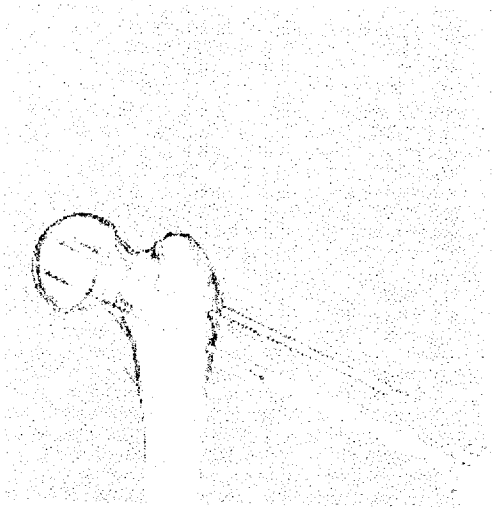
saving on time and cost



Step 1.
Insertion of Guide Pins

Select the appropriate Pin Guide and pattern and place the 3.2 mm Guide Pin into the femoral head across the fracture site.*
Insert further Guide Pins as required.
After checking the length and position of each Pin under image control, select the appropriate screw length by reading directly off the Calibrated Guide Pin or with the direct reading Pin Depth Gauge.

* When dense bone is present the lateral femoral cortex should be pre-drilled with the 3.2mm Gray "I" Bone Drill.*



Step 2.
Insertion of Guided Screws

Place the selected self cutting, self-tapping Asnis 2 Screw over each Guide Pin and drive into position with the Cannulated Hex Screw Power-Driving Shaft and/or the Cannulated Hex Hand Screwdriver. Remove the Guide Pins.

For those surgeons who prefer pre-tapping the femoral cortex, a Cannulated Tap is available.

*U.S. Patent No. 4,476,111

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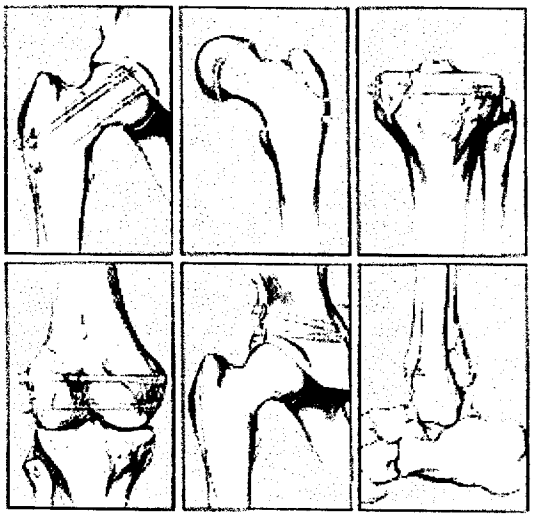
ASNIS 2

Indications and Applications

- Intracapsular Fractures of the Hip
- Slipped Capital Femoral Epiphyses
- Tibial Plateau Fractures
- Distal Femoral Condyle Fractures
- Pelvic and Acetabular Fractures
- Ankle, Elbow and Shoulder Fractures

Presentation

- Each screw is individually sterile packaged for immediate use and greater inventory control
- 20mm thread length provides an optimal number of threads for any application.
  16mm thread length screws have applications in the foot, elbow and shoulder
- Full range of sizes:
  35mm to 130mm in 5mm increments
  Thread length:
  16mm for sizes 35mm to 45mm
  20mm for sizes 55mm to 130mm



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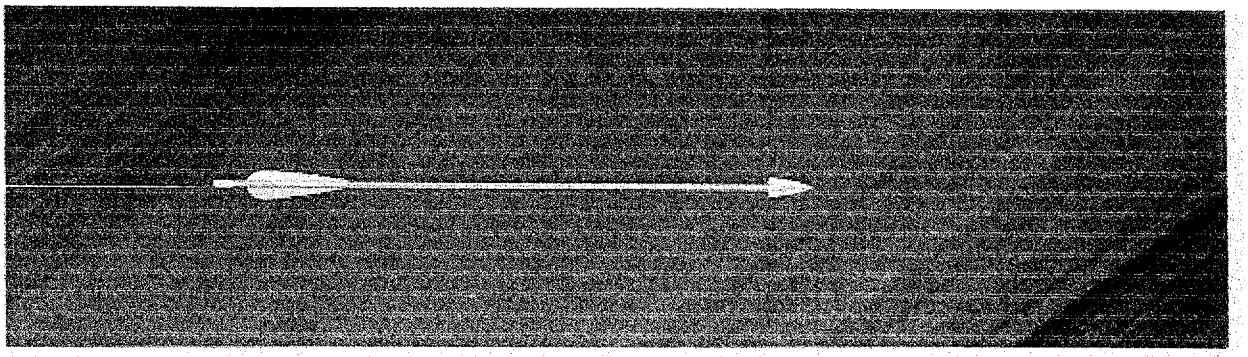
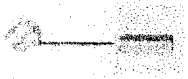


Ordering Information

Asnis 2 Guided Screw 6.5mm Thread Dia.					
Cat. No	Length mm	Thread Length mm	Cat. No	Length mm	Thread Length mm
3550-0-035	35	16	3550-0-085	85	20
3550-0-040	40	16	3550-0-090	90	20
3550-0-045	45	16	3550-0-095	95	20
3550-0-050	50	20	3550-0-0100	100	20
3550-0-055	55	20	3550-0-0105	105	20
3550-0-060	60	20	3550-0-0110	110	20
3550-0-065	65	20	3550-0-0115	115	20
3550-0-070	70	20	3550-0-0120	120	20
3550-0-075	75	20	3550-0-0125	125	20
3550-0-080	80	20	3550-0-0130	130	20

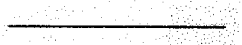
5680-6-000
Cancellous Screw Washer

3550-2-085
Quick Release Driver



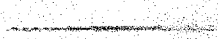
3550-2-010
Fixed Pin Guide (Triangular Pattern)

3550-2-040
Fixed Pin Guide (Diamond Pattern)



3550-2-100
3.2mm x 220mm Threaded Tip Guide Pin, Calibrated

3550-2-050
Cannulated Tip

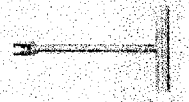


3550-2-150
3.2mm x 159mm Gray Bone Drill

3550-2-060
4.8mm Cannulated Hex Screwdriver

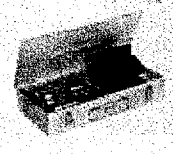
3550-2-070
4.8mm Cannulated Hex Screw Power Driving Shaft

5681-0-250
Pin Depth Gauge, 5mm to 100mm



3649-8-250
Screw Retractor

3550-2-000
Asnis 2 Storage/Sterilization Case



3550-2-100
5.2mm Cannulated Crown Drill

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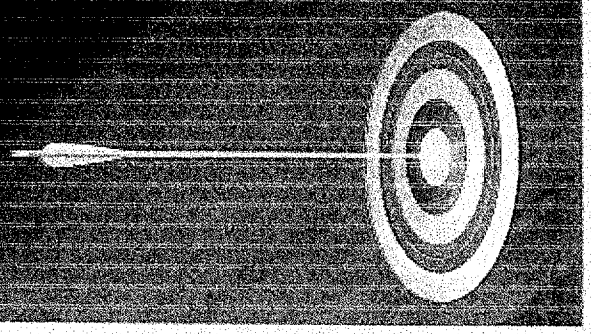
ASNIS 2

GUIDED SCREW SYSTEM



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Belgium Howmedica Belgium Zaventem
Tel (32) 720 [illegible]
Brazil Howmedica Brasil, Sao Paulo
Tel (55) 11 [illegible]
Canada Howmedica Canada, Guelph Tel (519) [illegible]
Colombia Howmedica Colombia, Bogota Tel (57) [illegible]
Denmark Howmedica Danmark, Hvidovre Tel (45) [illegible]
East Europe Howmedica EMEA, London Tel (44) [illegible]
Finland Howmedica, Helsinki Tel (358) [illegible]
France Howmedica, Lyon Tel (33) [illegible]
Germany Howmedica Deutschland, Kiel Tel (49) [illegible]
Hong Kong Howmedica, Hong Kong Tel (852) [illegible]
India Howmedica India, Mumbai Tel (91) [illegible]
Italy Howmedica Italia, Rome Tel (39) [illegible]
Japan Howmedica Japan, Tokyo Tel (81) [illegible]
Korea Howmedica, Seoul Tel (82) [illegible]
Malaysia Pfizer Pharmaceuticals, Selangor Tel (603) [illegible]
Middle East Howmedica EMEA, London Tel (44) [illegible]
Netherlands Howmedica Netherlands, Hoofddorp
Tel (31) [illegible]
New Zealand Howmedica New Zealand, Auckland
Tel (64) [illegible]
Norway Howmedica Norway, Oslo Tel (47) [illegible]
Portugal Howmedica Portugal, Lisbon Tel (351) [illegible]
Philippines Howmedica Philippines, Makati
Tel (63) [illegible]
Singapore Pfizer Pharmaceuticals, Singapore Tel (65) [illegible]
Spain Howmedica Iberica SA, Madrid Tel (34) [illegible]
Sweden Pfizer Medical Sweden, Malmo Tel (46) [illegible]
Switzerland Pfizer Switzerland, Geneva Tel (41) [illegible]
Thailand Howmedica, Bangkok Tel (662) [illegible]
Taiwan R.O.C. Howmedica, Taipei Tel (886) [illegible]

AS-01/11/97

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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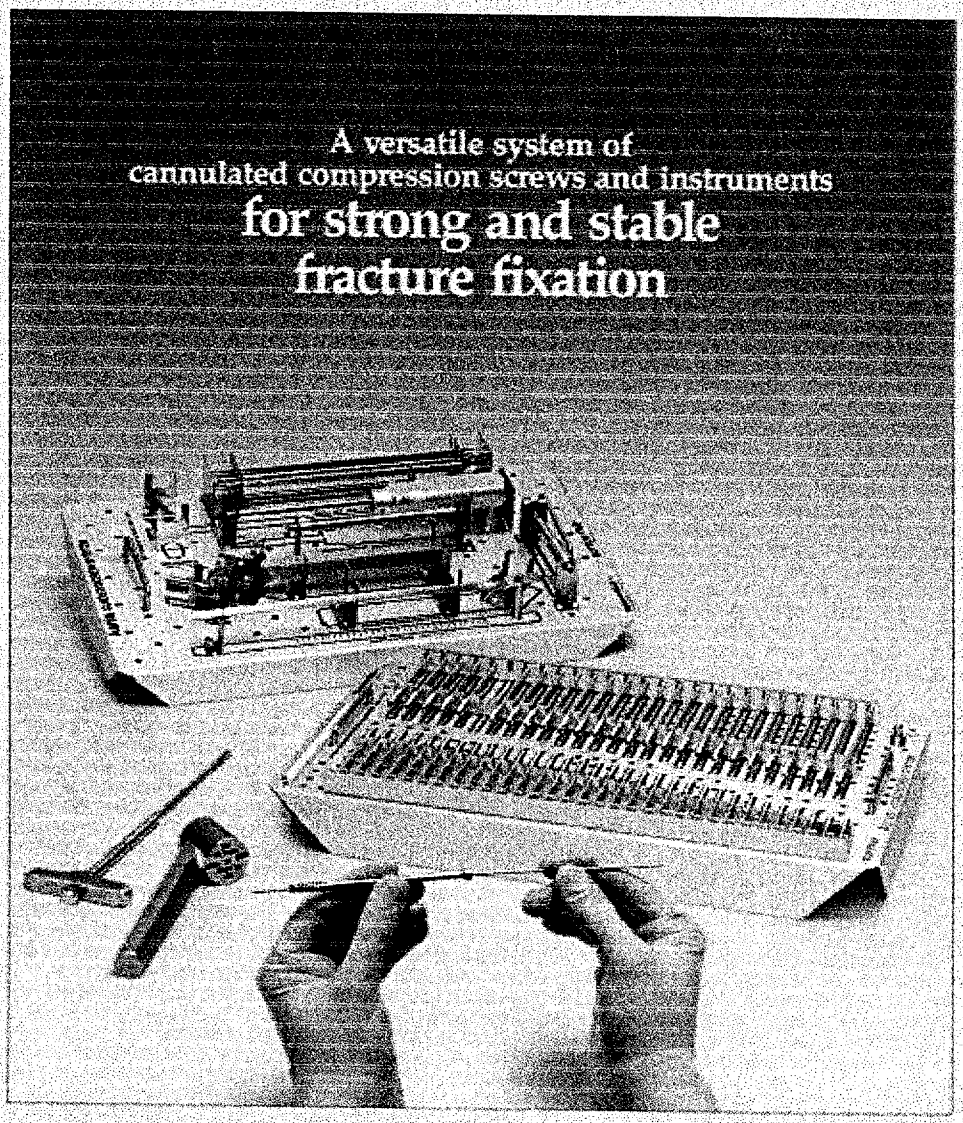
H O W M E D I C A



The Asnis Guided Screw System*

*U.S. Patent Nos. 6,343,527 and 6,450,635

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

The Asnis Guided Screw System

Stainless Steel (316 LVM)

Ideal for intracapsular fractures of the hip...and now a variety of other trauma indications

The Asnis Guided Screw System of cannulated compression screws is ideal for intracapsular fractures of the hip. The 6.4mm buttress threads and the superior bending, torque and pullout strength of the Asnis Guided Screw versus Knowles and Gouffon pins or the AO-type cancellous screw* make the Asnis screw an excellent choice for a variety of trauma indications in areas other than the hip.

Indications:

- **Intracapsular fractures of the hip**
- **Slipped capital femoral epiphyses**
- **Tibial plateau fractures**
- **Distal femoral condyle fractures**
- **Ankle, elbow and shoulder fractures**

- **Cannulation allows accurate placement of the screws over a guide pin**, providing better control and management of fracture fragments.
- **Comparatively small size of the Asnis Guided Screws allows multiple fixation points** so that placement can be achieved in the best available bone stock, such as denser peripheral bone, with minimal bone displacement.
- **Multiple fixation points minimize the risk of rotation** both intraoperatively and after implantation.
- **Asnis Guided Screw System Instruments offer the advantage** of placing a guide pin **prior** to the implant to assure proper positioning.
- **Fixed and Adjustable Pin Guides assure parallel placement** for secure compression and impaction.
- **Guide Pin Assembly allows screw lengths to be changed intraoperatively** without the potential loss of fixation or reduction to assure that the appropriate implant length is used.

* Data on file at Howmedica

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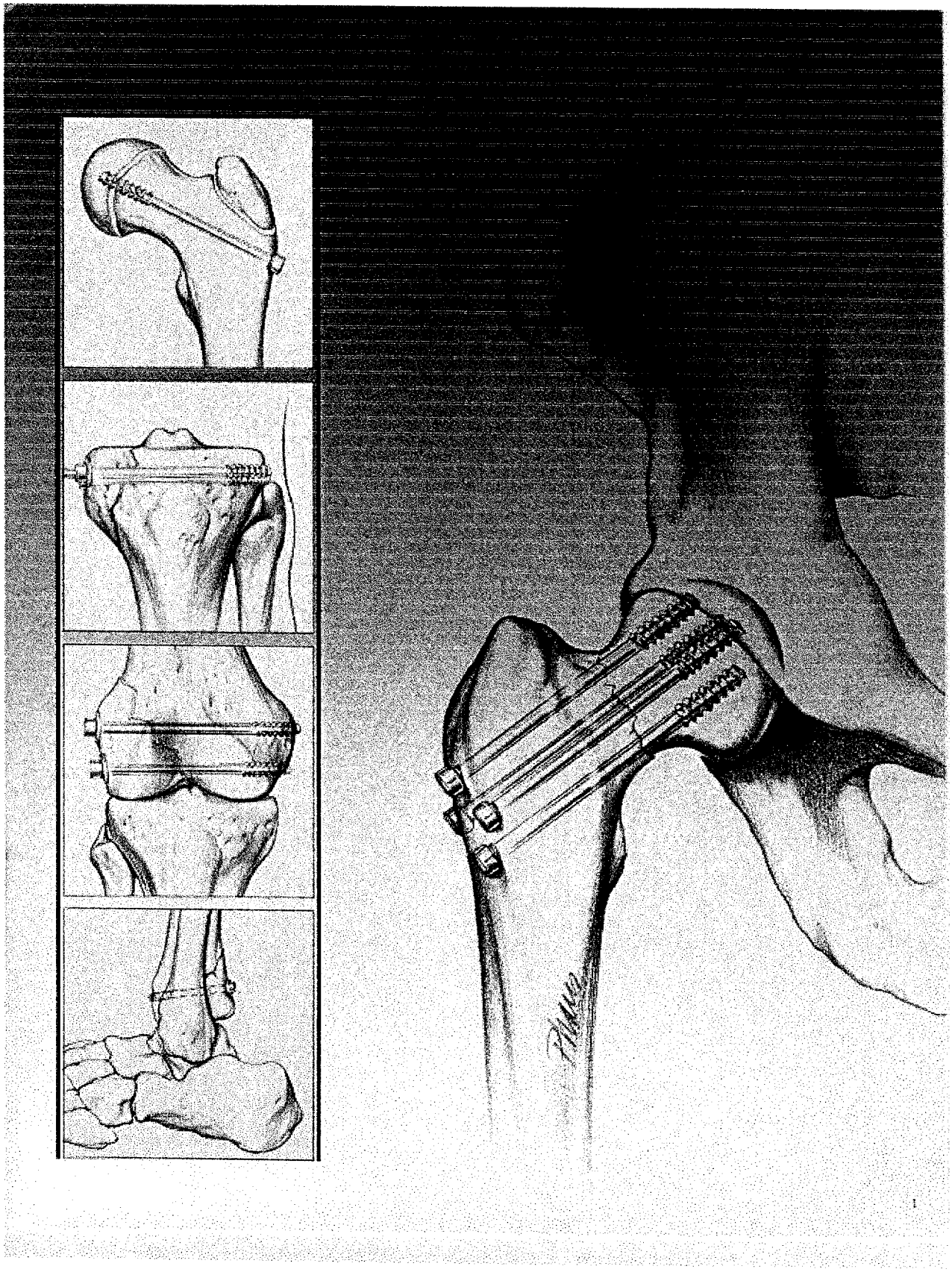


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

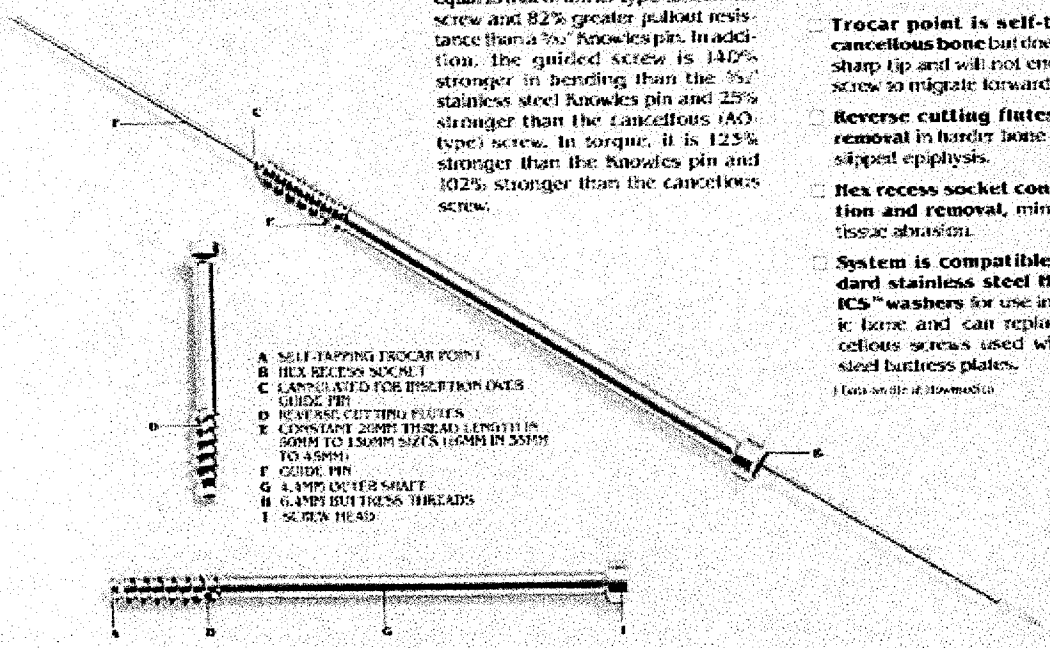
The Asnis Guided Screw System

Designed for strong and stable fixation of fracture fragments with minimal bone displacement

CLINICAL FEATURES & BENEFITS:

- **Cannulation of the screw allows for accurate placement over a guide pin.**
- **4.4mm outer shaft diameter is smaller than that of compression hip screws,** displacing less bone and minimizing reduction of blood supply.
- **6.4mm buttress threads offer excellent fixation in cancellous bone.** Laboratory studies† show a pullout resistance approximately equal to that of an AO-type cancellous screw and 82% greater pullout resistance than a 5/32" Knowles pin. In addition, the guided screw is 140% stronger in bending than the 5/32" stainless steel Knowles pin and 25% stronger than the cancellous (AO-type) screw. In torque, it is 125% stronger than the Knowles pin and 102% stronger than the cancellous screw.
- **Available in 20 lengths ranging from 35mm to 130mm in 5mm increments.** The 20mm thread length in 35mm to 130mm screws ensures that the threads will not cross the fracture site in intracapsular hip fractures. This allows compression and maintains bone contact with later settling of the fracture. In the 35mm to 55mm screws, the thread length is decreased to 16mm.
- **Root diameter of the screw is the same as that of the shank,** avoiding a stress concentration at the junction of the thread and shaft.
- **Trocar point is self-tapping in cancellous bone** but does not have a sharp tip and will not encourage the screw to migrate forward.
- **Reverse cutting flutes facilitate removal** in harder bone such as in a slipped epiphysis.
- **Hex recess socket controls insertion and removal,** minimizing soft tissue abrasion.
- **System is compatible with standard stainless steel Howmedica® ICS™ washers** for use in osteoporotic bone and can replace the cancellous screws used with stainless steel buttress plates.

† Data on file at Howmedica



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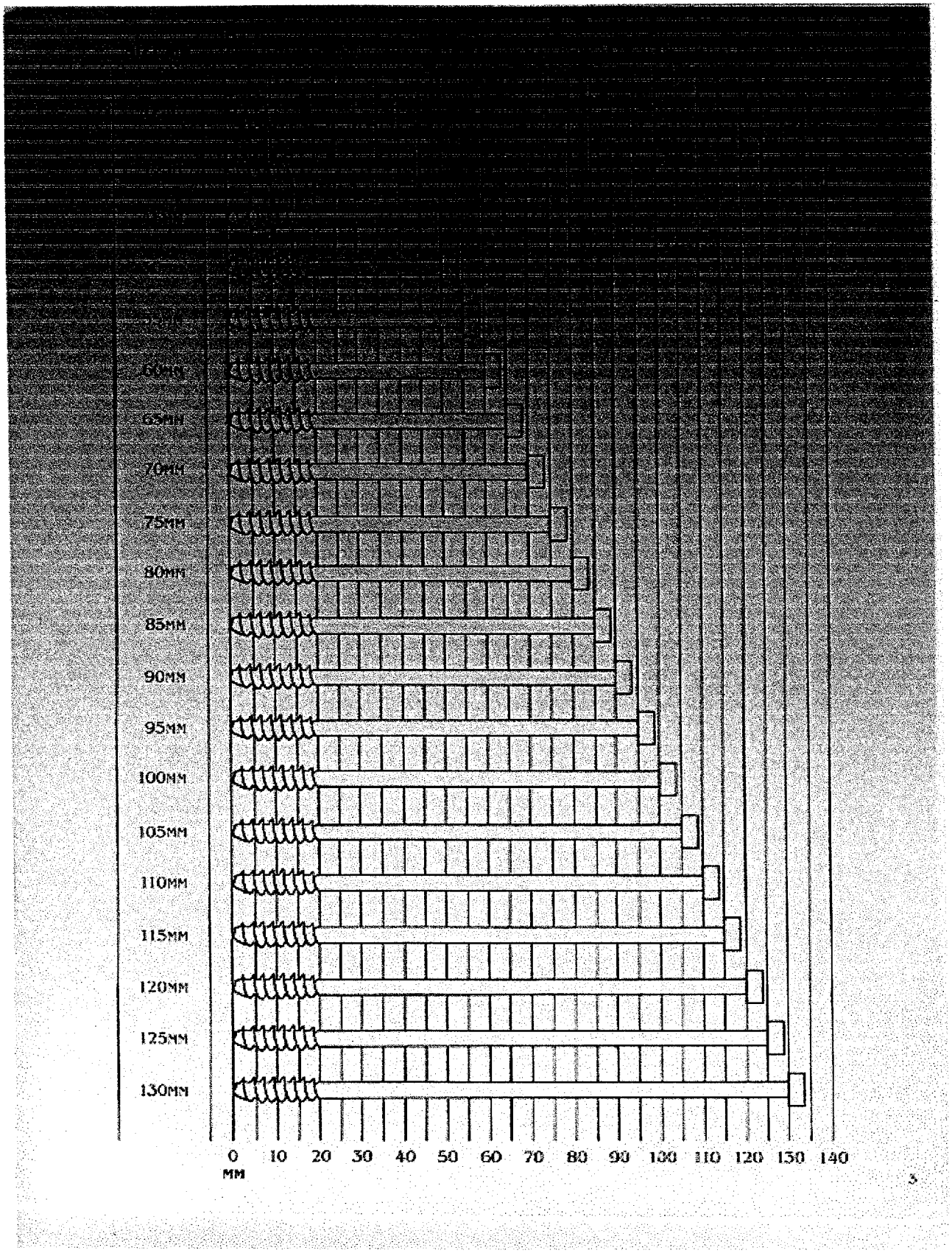

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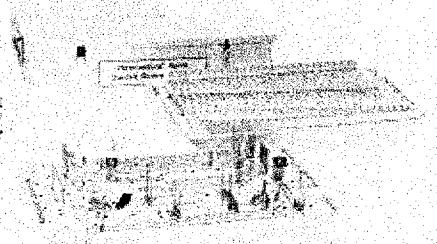
The Asnis Guided Screw System Instruments

Designed to assure accurate placement and proper positioning of Asnis cannulated screws



STORAGE & STERILIZATION CASE
SCREW TRAY
INSTRUMENT TRAY

CLINICAL FEATURES & BENEFITS:

- Guide Pin Assembly facilitates accurate screw placement.
  - Outer sleeve supports the guide pin while reaming for shaft diameter of the screw as the guide pin is inserted.
  - Smaller diameter guide pin allows smaller screw cannulation for maximum screw strength.
- System accommodates a range of fracture modes through the use of fixed and adjustable guides which assure parallel placement of screws in a variety of configurations.
- Parallel placement of screws assures compression and impaction of intracapsular fractures.
- Screw lengths can be freely interchanged intraoperatively without losing fixation or reduction.

Cannulation: The Basic Concept

Note: The following figures are intended merely as an illustration of the basic concept of guided screws; they are not intended to be used as a surgical technique.

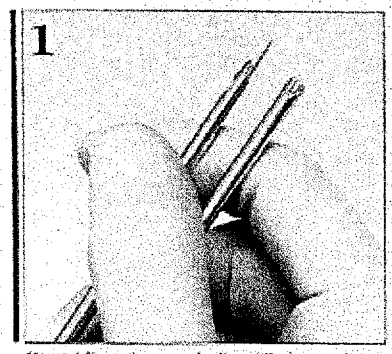


Figure 1. Shows the proper loading of the inner and outer components of the Guide Pin Assembly. The back-end of the inner pin has a flat side which must be against the flat side of the back (slide) outer sheath. In this position the two pins are locked together and work as a unit. When the inner pin's back end is flush with the outer pin's, the locking mechanism is released and each pin can move independently.

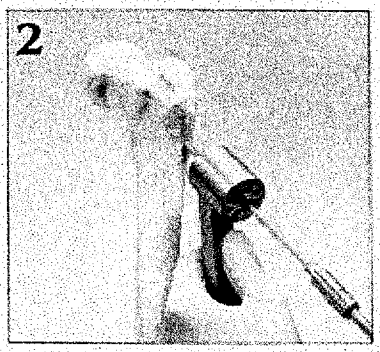


Figure 2. After prefilling the cortex with a 3/32" drill bit, the Pin Driver is used to insert the Guide Pin Assembly. The cortex hole of the Fixed Pin Guide is used to steady the drill and the Guide Pin Assembly.

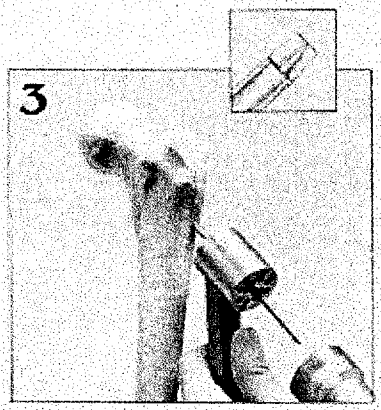


Figure 3. The inner pin of the assembly is then tapped gently with a mallet so it is flush with the outer component. This advances the inner pin 5mm, locking it in subchondral bone, and disengages the inner from the outer component. The outer component can then be removed with the pin driver, leaving the inner guide pin in place.

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A 9" (230MM) DRILL
B PIN DEPTH GAUGE
C CANNULATED TAP
D ADJUSTABLE PIN GUIDE
E FIXED PIN GUIDE, DIAMOND PATTERN
F FIXED PIN GUIDE, TRIANGULAR PATTERN
G PIN DRIVER
H ¼" CANNULATED HEX SCREWDRIVER
I GUIDE PIN ASSEMBLY

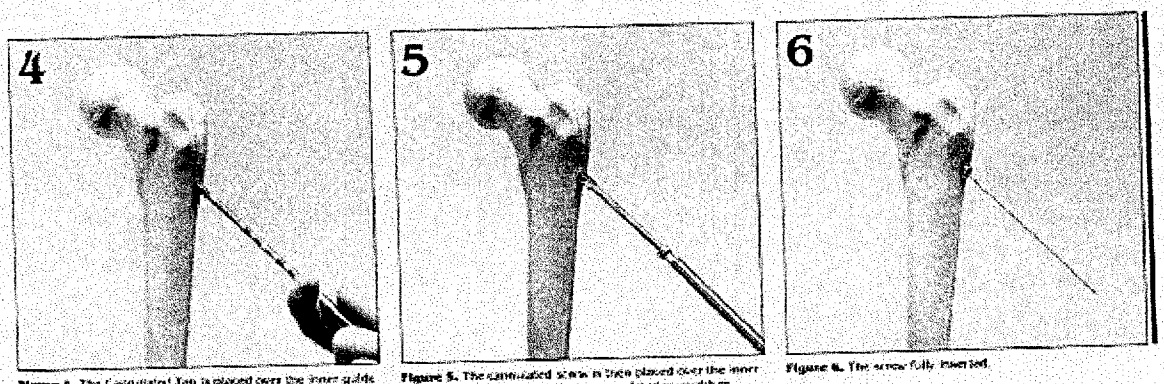

Figure 4. The Cannulated Tap is placed over the inner guide pin and used to tap the outer cortex only.

Figure 5. The cannulated screw is then placed over the inner guide pin and tightened with the cannulated screwdriver.

Figure 6. The screw fully inserted.

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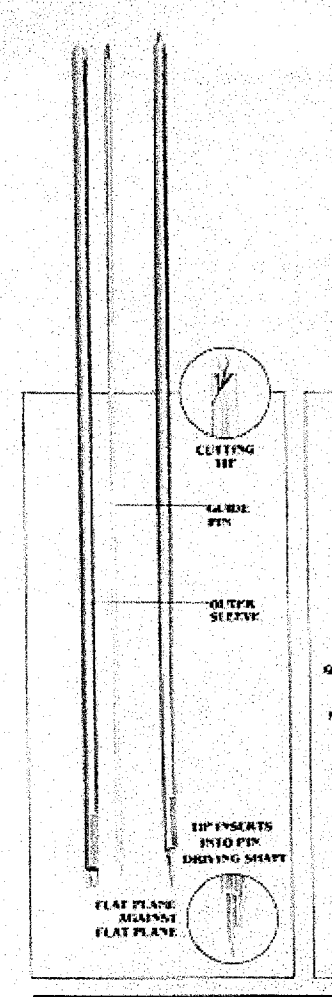
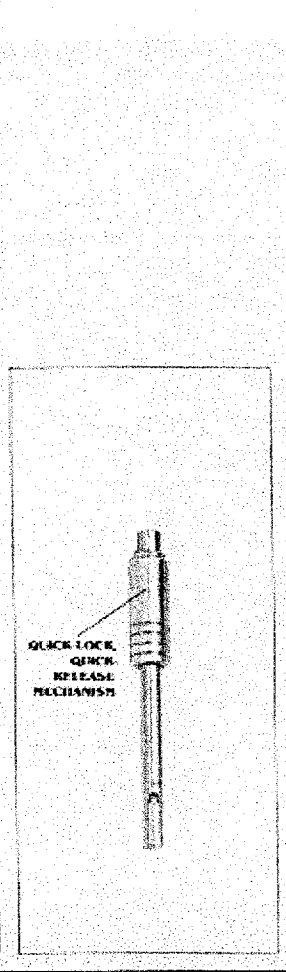
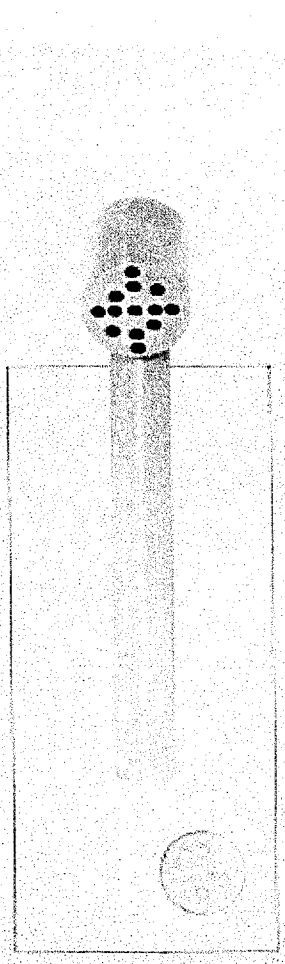
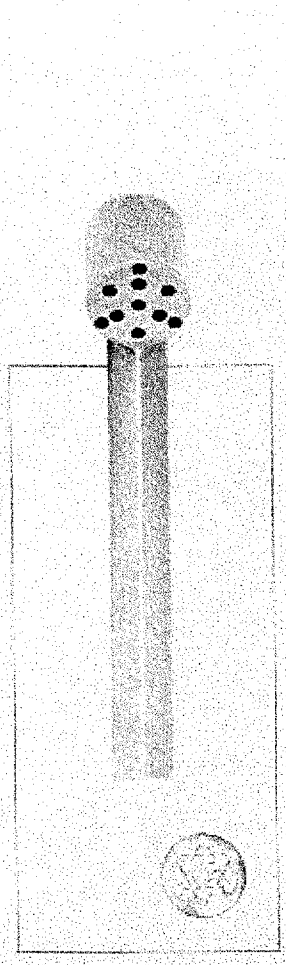
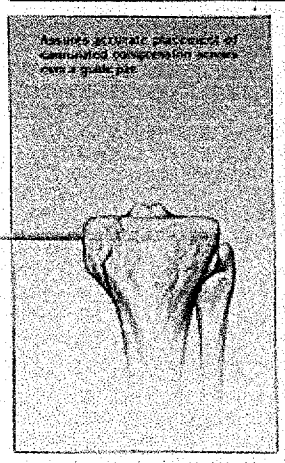


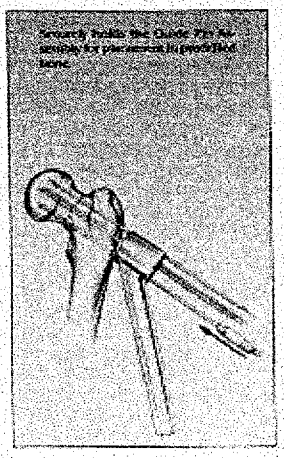


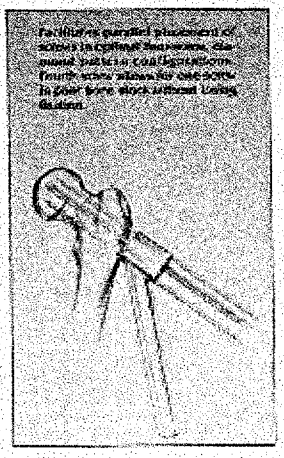


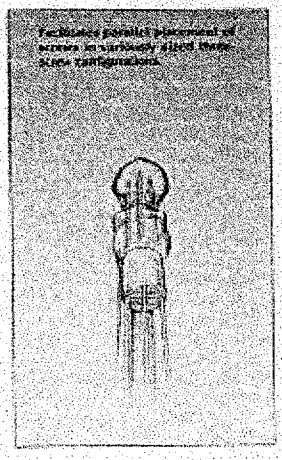


GUIDE PIN ASSEMBLY	PIN DRIVING SHAFT	FIXED PIN GUIDE, DIAMOND PATTERN	FIXED PIN GUIDE, TRIANGULAR PATTERN









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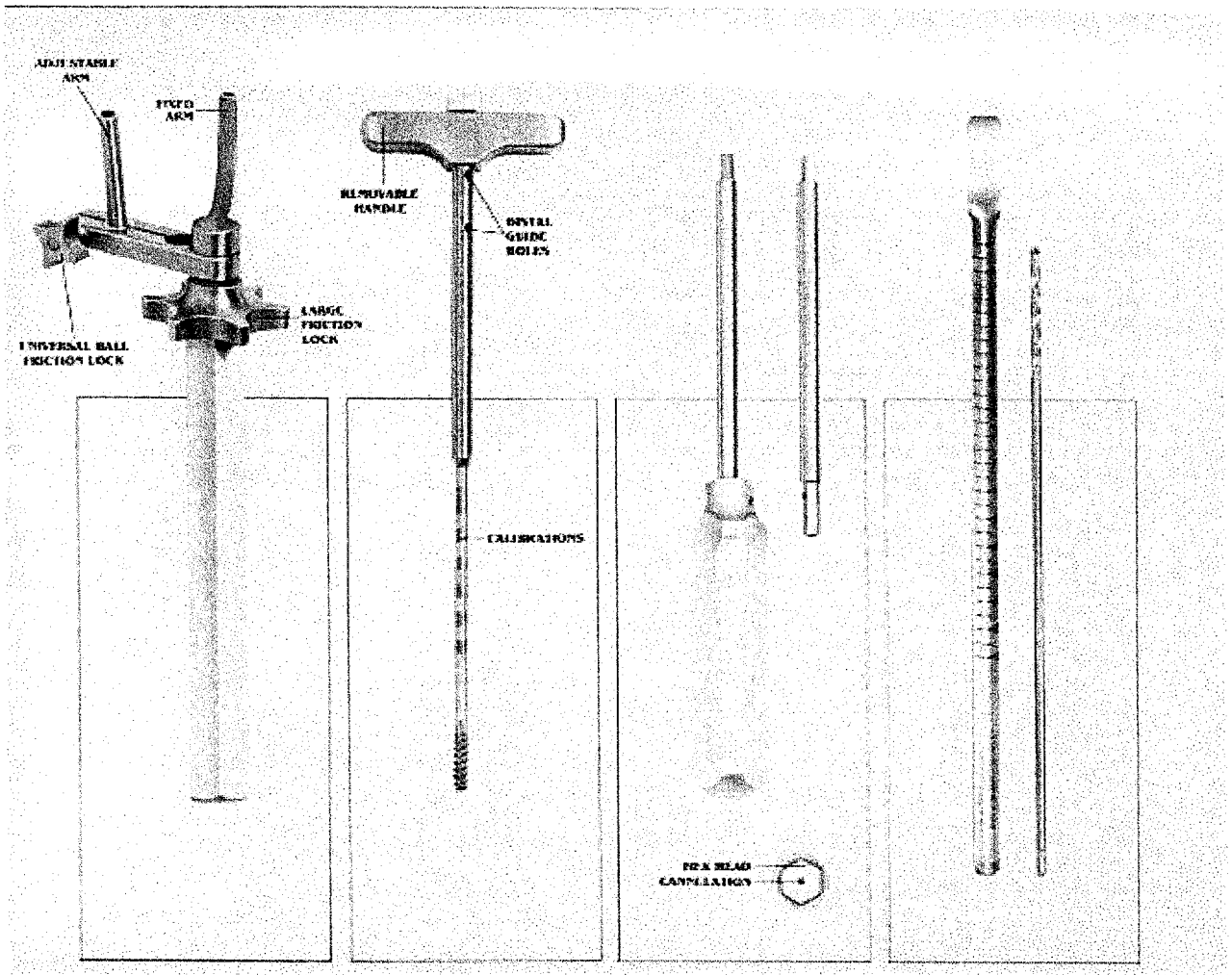
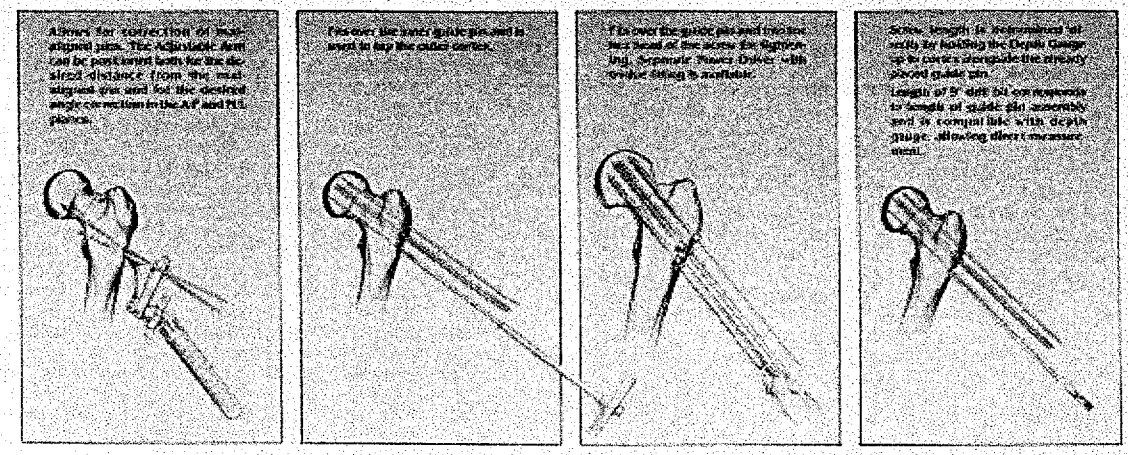


ADJUSTABLE PIN GUIDE	CANNULATED TAP	CANNULATED HEX SCREWDRIVER & POWER DRIVER	DEPTH GAUGE & 9' DRILL BIT



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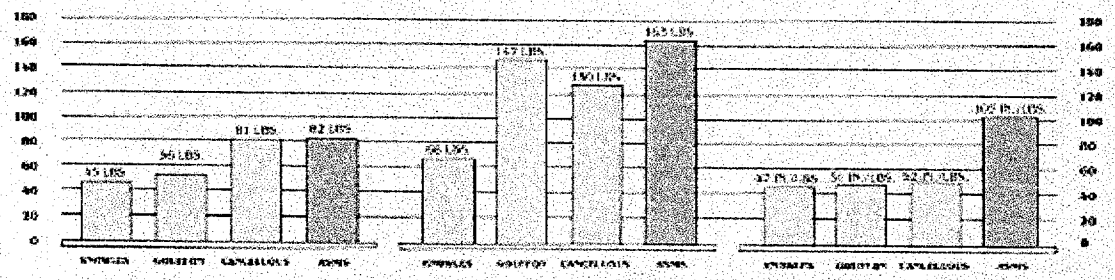
The Asnis Guided Screw System

Stainless Steel (316 LVM)

Summary

- **Cannulation allows accurate placement of the screws over a guide pin,** providing better control and management of fracture fragments.
- **6.4mm buttress threads offer excellent fixation in cancellous bone,** with superior pullout, bending and torque strength.†
- **4.4mm outer shaft diameter is smaller than that of compression hip screws,** displacing less bone and minimizing reduction of blood supply.
- **Comparatively small size allows multiple fixation points** so that placement can be achieved in the best available bone stock.
- **Multiple fixation points minimize the risk of rotation** both intraoperatively and after implantation.
- **Reverse cutting flutes facilitate removal** in harder bone such as in a slipped capital femoral epiphysis.
- **Available in 20 lengths ranging from 35mm to 130mm in 5mm increments.**
- **System is compatible with standard stainless steel Howmedica* ICS™ washers** for use in osteoporotic bone and can replace the cancellous screws used with stainless steel buttress plates.
- **Asnis Guided Screw System instruments offer the advantage** of placing a guide pin **prior** to the implant to assure proper positioning.
- **Fixed and Adjustable Pin Guides assure parallel placement** for secure compression and impaction.
- **Guide Pin Assembly allows screw lengths to be changed intraoperatively** without the loss of fixation or reduction to assure that the appropriate implant length is used.

* Patent Pending Howmedica



FULLOUT STRENGTH | BENDING STRENGTH | TORQUE STRENGTH

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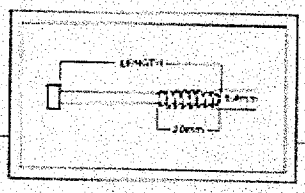
Asnis Guided Screws, Cannulated
6.4mm Thread Dia., 20mm Thread Length

Cat. No.	Length mm
3549-1-035**	35
3549-1-040**	40
3549-1-045**	45
3549-1-050	50
3549-1-055	55
3549-1-060	60
3549-1-065	65
3549-1-070	70
3549-1-075	75
3549-1-080	80

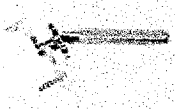
** 16mm Thread Length

Asnis Guided Screws, Cannulated
6.4mm Thread Dia., 20mm Thread Length

Cat. No.	Length mm
3549-1-085	85
3549-1-090	90
3549-1-095	95
3549-1-100	100
3549-1-105	105
3549-1-110	110
3549-1-115	115
3549-1-120	120
3549-1-125	125
3549-1-130	130



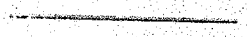
5686-6-000	Cancellous Screw Washer (optional)



3849-2-100
Adjustable Pin Guide

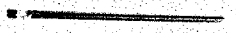
3849-3-000
Fixed Pin Guide (Triangular Pattern)

3849-3-400
Fixed Pin Guide (Diamond Pattern)

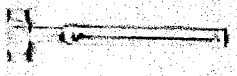


3849-5-040
4.0mm Dia. Drill, 230mm Length with Trimmer Fitting (Individually Packaged)

3849-4-000
Guide Pin Assembly††



3849-8-100
Pin Depth Gauge, 0mm to 150mm

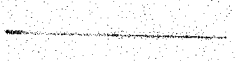


6609-8-003
KOOL-GRIP Mallet—Small

3849-5-000
Pin Driver

3849-8-050
Screw Retractor

3849-6-090
Guide Pin Sheath

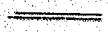


3849-7-000
Tap

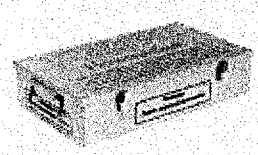
3849-7-100
Tap Handle

3849-7-200
Tap Handle Screw

3849-8-000
¼" Cannulated Hex Screwdriver



3849-6-000
Drive Shaft



3849-1-100
Asnis Guided Screw System Storage and Sterilization Case with Two Trays (Empty)

Screw Tray Capacity: 50 Asnis Screws

2 each	30mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm 110mm, 115mm, 120mm, 125mm, 130mm
3 each	70mm, 105mm
4 each	100mm
5 each	75mm, 80mm, 85mm, 90mm, 95mm

†U.S. Patent No. 4,951,677
††U.S. Patent No. 4,450,835

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Howmedica

Finding solutions through advanced technology

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FRACTURE MANAGEMENT

The Herbert™ Bone Screws for Small Bone Fractures

Herbert/Whipple™ Bone Screws

Herbert Mini Bone Screws

Herbert Bone Screws

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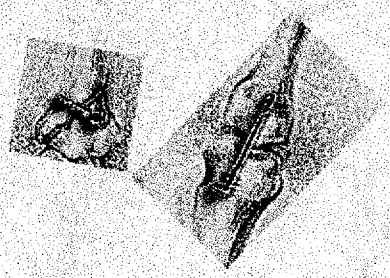
Double Thread. No Head
The Exclusive Herbert Bone Screw Design.

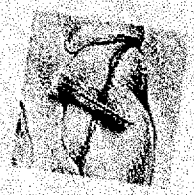
The exclusive, patented* design of the *Herbert* Bone Screw offers a unique opportunity for the effective treatment of small-bone and intra-articular fractures. This system provides significant advantages over fixation techniques using conventional bone screws or K-wires. Fracture reduction and compression are combined to provide rigid internal fixation.

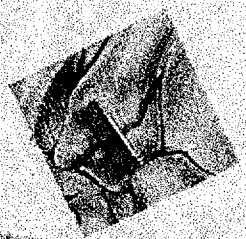
Keys to the design are the double threads, with a different pitch on the distal and proximal ends.

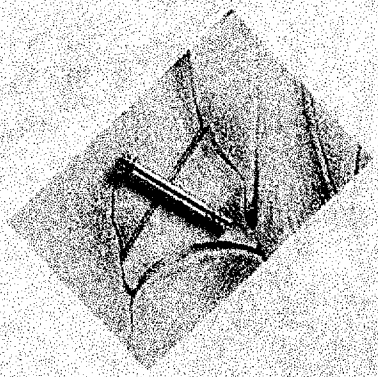
Because of this pitch differential, the leading threads penetrate the bone faster than the trailing threads, which reduces and compresses the fracture as the screw is being inserted.

These specialized screws have no heads, so they can be inserted through articular cartilage and buried below the bone surface. Thus, the *Herbert* implants are ideal for intra-articular use because nothing protrudes above the bone surface to interfere with articulation or soft tissue. In addition, the short









*U.S. Patent 4,175,556

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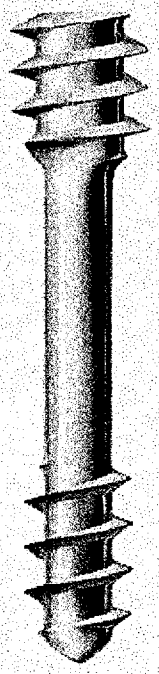
thread length and small diameters allow for optimum fixation of very small bone fragments.

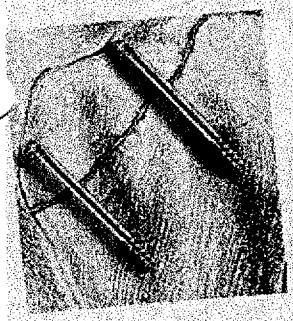
The *Herbert* Bone Screw is not only unique in its design, but also in its versatility. Originally developed for use in treating scaphoid fractures, the expanded system is now used in a wide range of small bone and intra articular procedures.

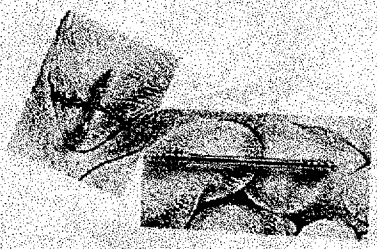
Implants are manufactured from *Titanium*®Ti-6Al-4V Alloy which provides excellent strength and biocompatibility. The screws are inert and, in most cases, removal has not been necessary.

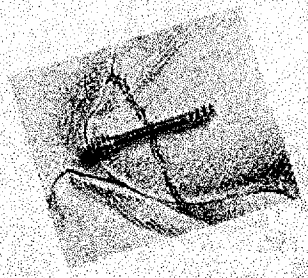
This small-bone fixation system includes the *Herbert* Bone Screw, the *Herbert/Whipple* Bone Screw, and the *Herbert* Mini Bone Screw. The *Herbert* Bone Screw is the first system of specialized bone screws that meet the needs of all small-bone fractures.



Trailing threads oppose the leading threads, slowing penetration and pulling the fragments together as the screw is inserted, causing reduction.







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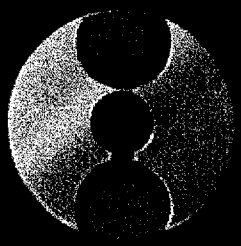
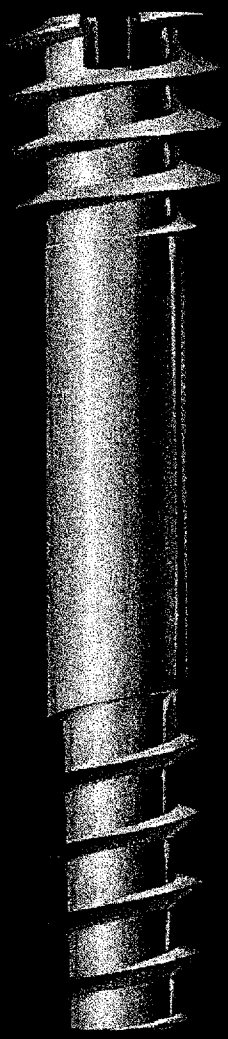
The Herbert/Whipple Bone Screws**



Double pin drive provides a positive screw/screwdriver interface.

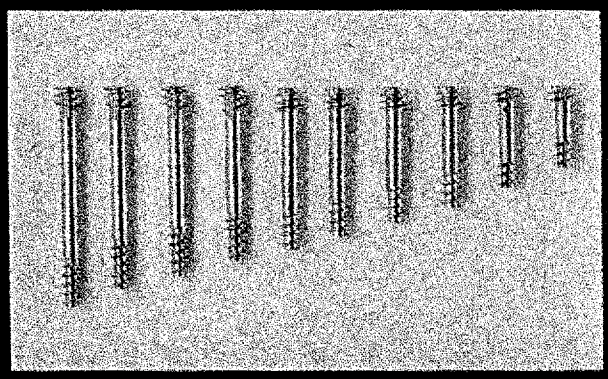


The *Herbert/Whipple* Bone Screw is a small-diameter (3.0/3.9 mm), cannulated device for use in small-bone fractures and arthroscopic procedures.

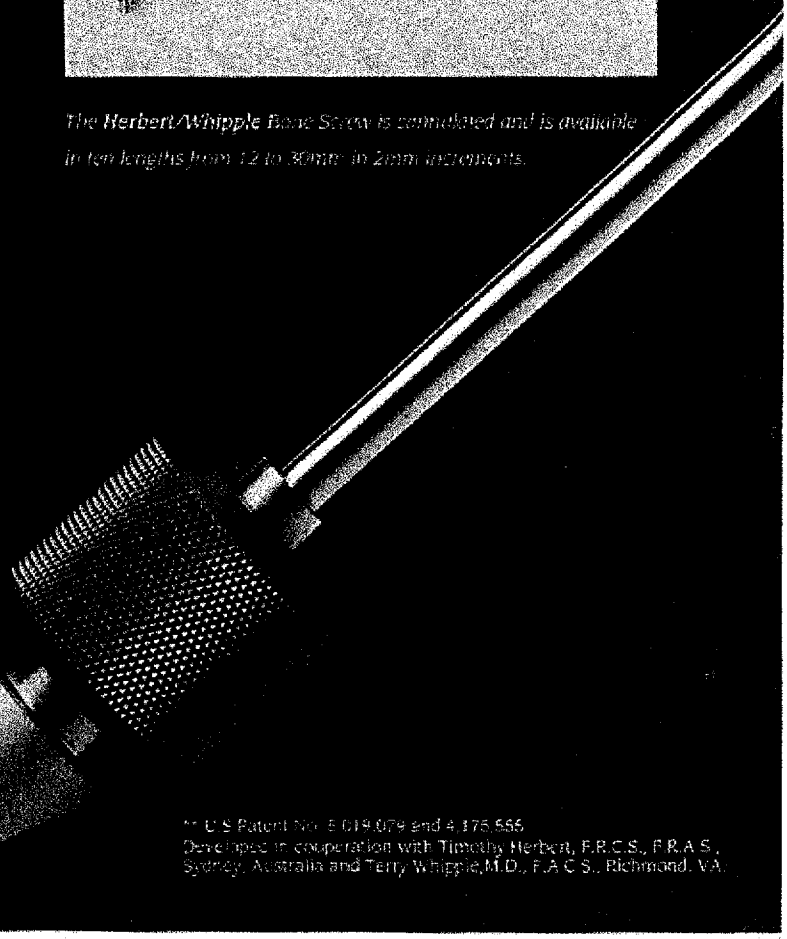
A K-wire is used to provide initial fracture fixation. Correct positioning of the wire can be confirmed with an x-ray. The instruments and cannulated screws are then inserted over the K-wire for accurate implant placement.

The trailing end of the implant has a double-pin socket drive for a secure interface between the screw and the screwdriver.

Both leading and trailing threads are self-tapping for ease of insertion.



*The **Herbert/Whipple** Bone Screw is cannulated and is available in ten lengths from 12 to 30mm in 2mm increments.*



** U.S. Patent No. 5,019,079 and 4,175,555
Developed in cooperation with Timothy Herbert, F.R.C.S., F.R.A.S., Sydney, Australia and Terry Whipple, M.D., F.A.C.S., Richmond, VA.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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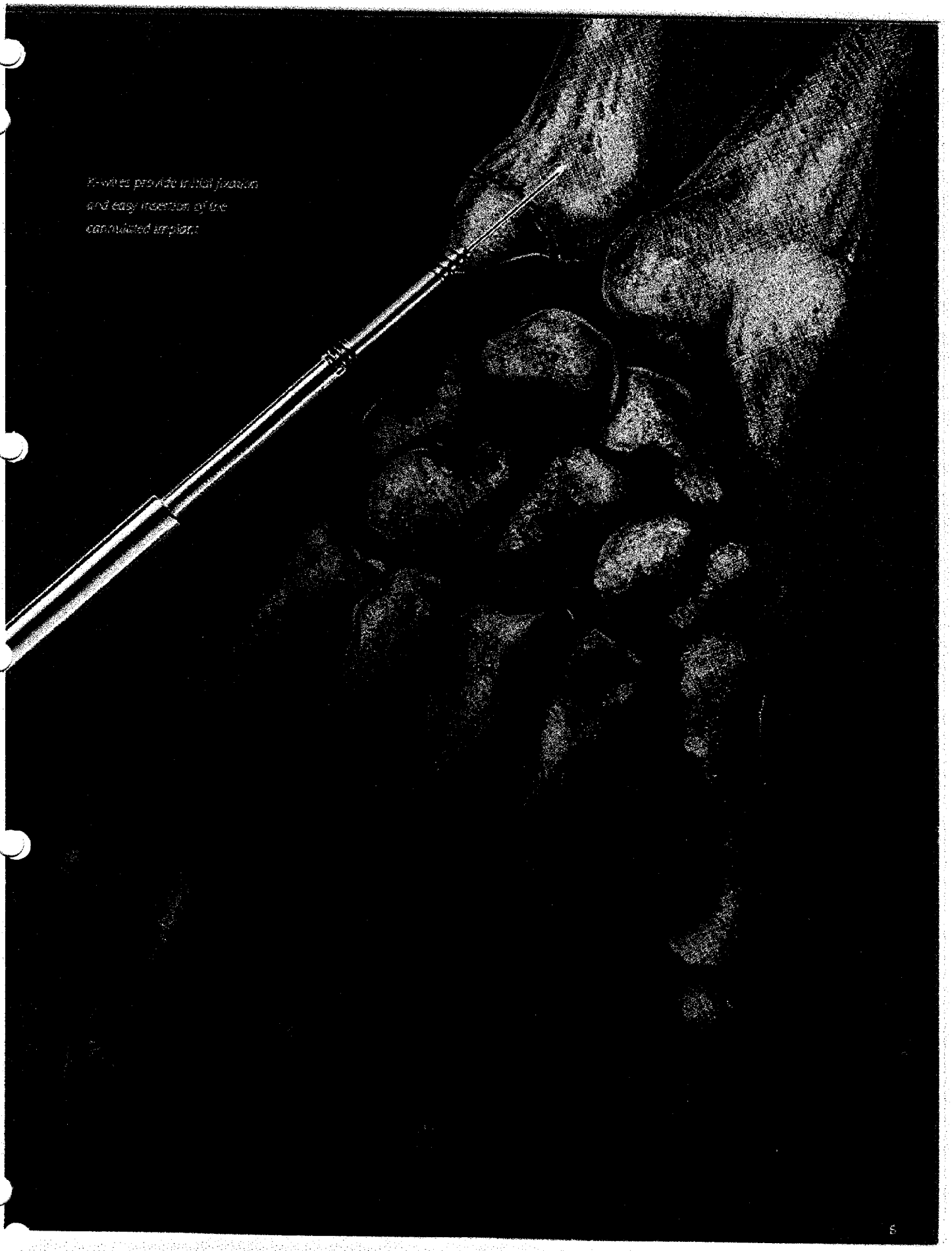

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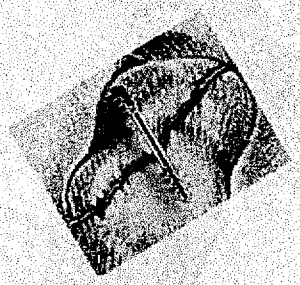
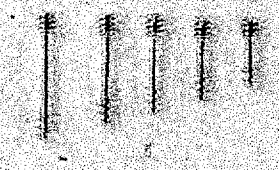
Herbert Mini Bone Screws†

The *Herbert Mini*† Bone Screw is ideal for use in fractures of the hands and fingers, or in fractures of small fragments. The small thread diameters (2.5/3.2 mm) provide excellent bone purchase and allow use in very small fragments. The screw is available in five lengths from 10 to 18 mm in 2 mm increments. The trailing end of the implant has a hex socket drive for a secure interface between the screw and the screwdriver.





The Herbert Mini Bone Screw is available in five lengths from 10 to 18 mm in 2 mm increments.

† *Herbert Mini* Bone Screws available third quarter 1992.
‡ U.S. Patent No. 4,175,555

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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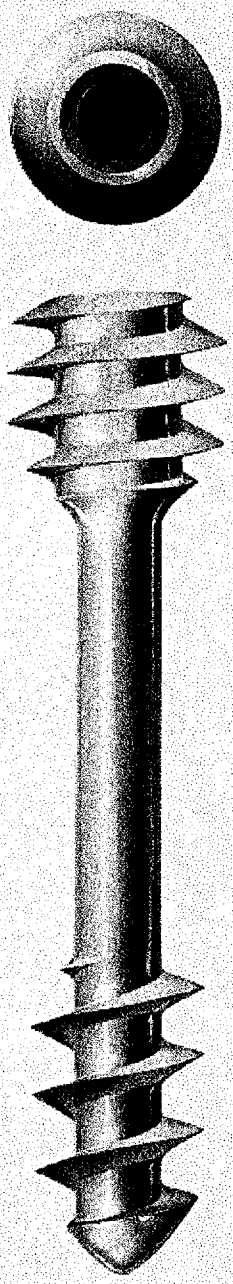
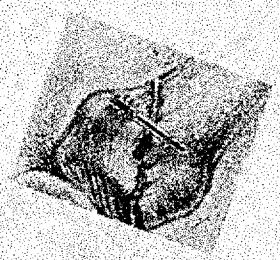


Extra small diameter threads allow screws to be used in very small fragments.



Developed in cooperation with Timothy Herbert F.R.C.S. F.R.A.C.S. Sydney, Australia

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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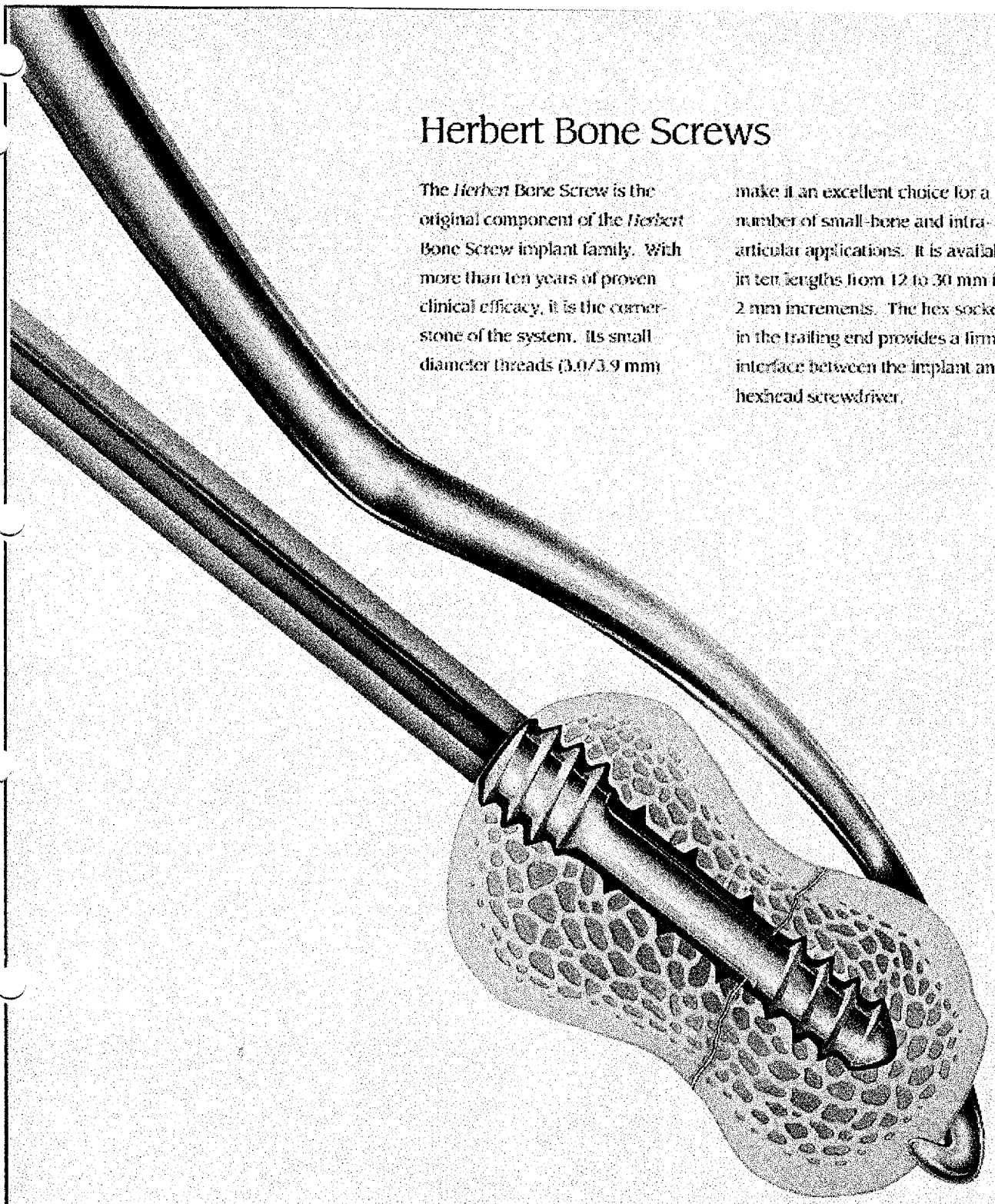
Herbert Bone Screws

The *Herbert* Bone Screw is the original component of the *Herbert* Bone Screw implant family. With more than ten years of proven clinical efficacy, it is the cornerstone of the system. Its small diameter threads (3.0/3.9 mm) make it an excellent choice for a number of small-bone and intra-articular applications. It is available in ten lengths from 12 to 30 mm in 2 mm increments. The hex socket in the trailing end provides a firm interface between the implant and hexhead screwdriver.



Developed in cooperation with Timothy Herbert, F.R.C.S., F.R.A.C.S., Sydney, Australia

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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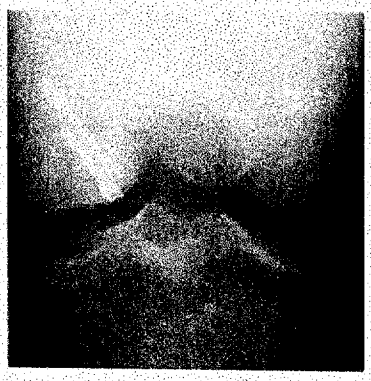
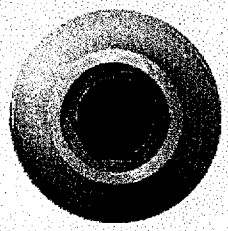
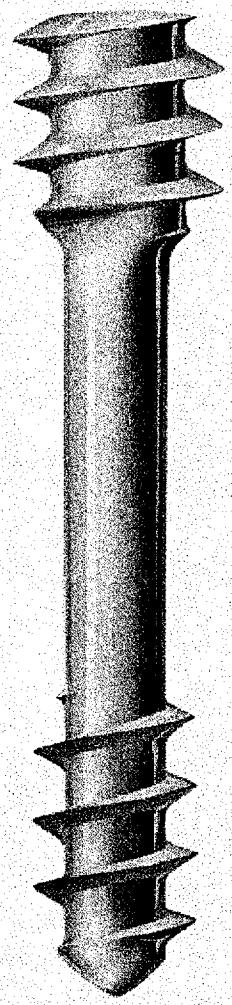


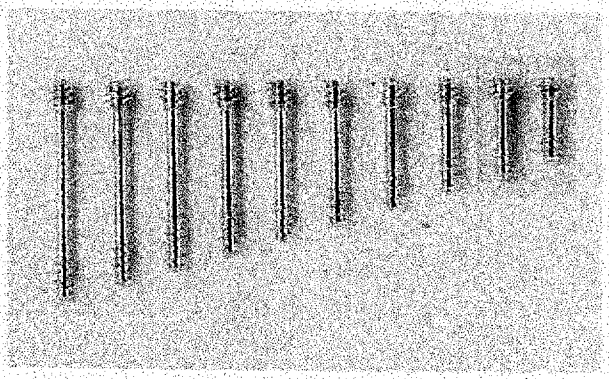
Management of osteochondrous lesions, as the result of osteochondritis dissecans, is facilitated by use of the **Herbert** *Bone Screw.*



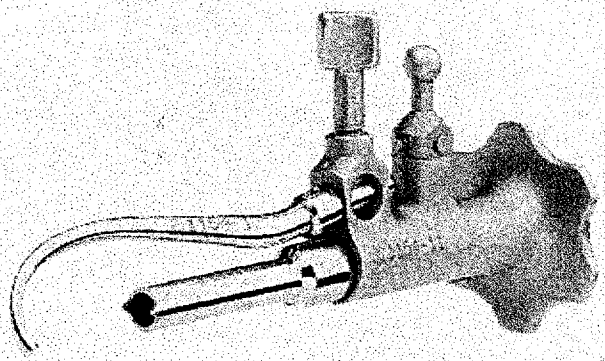
Sure fixation is achieved with a hexhead screw-driver.



The **Herbert** *Bone Screw is an excellent choice for scaphoid and other small bone fractures.*



The **Herbert** *Bone Screw is available in ten lengths from 12 to 20 mm in 2 mm increments.*



The Hatch Alignment Guide holds bone fragments firmly together, ensuring accurate insertion of the instruments and implants.*

* U.S. Patent 3,867,932

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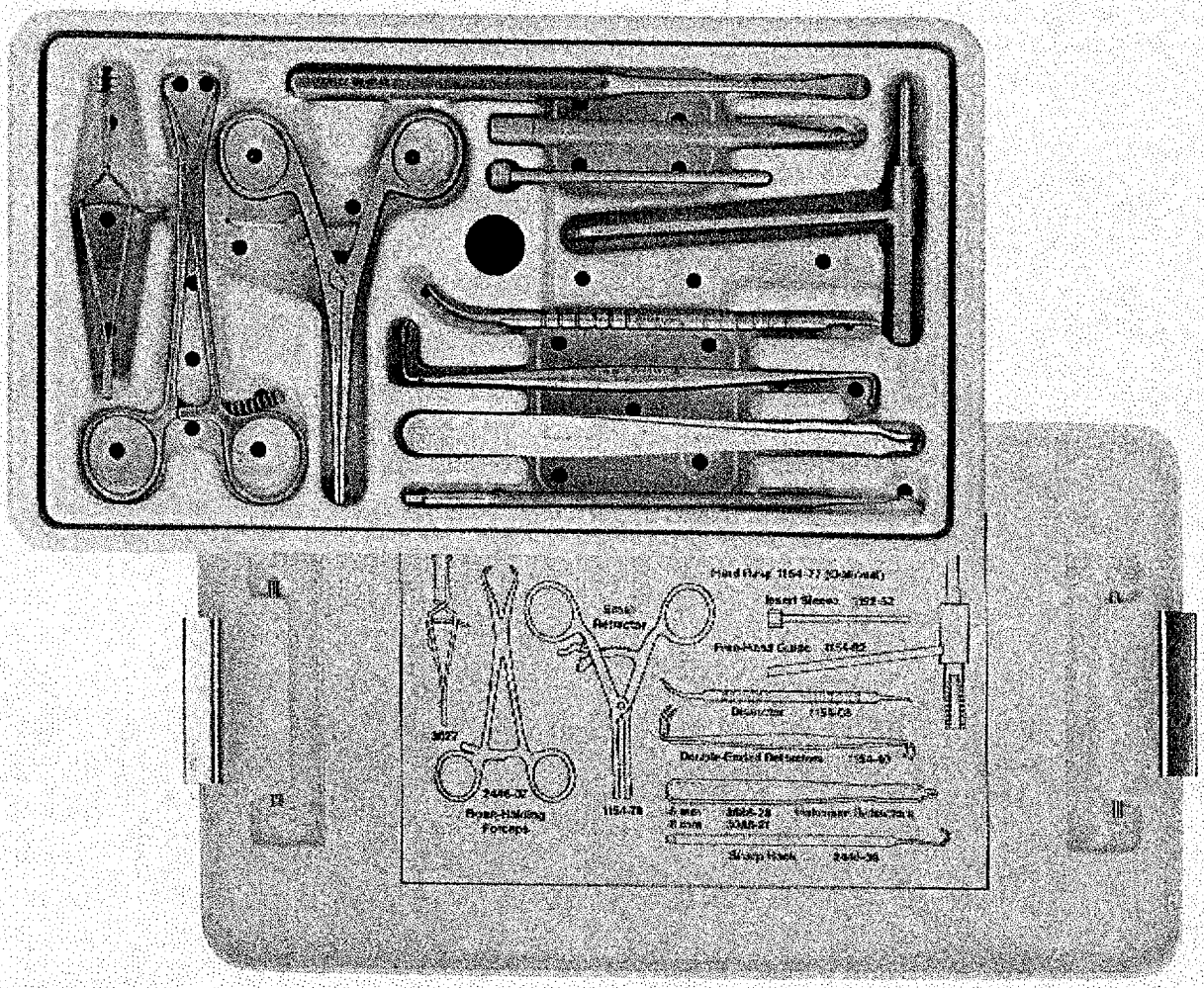
Convenient, Organized Trays in a Single Case

The *Herbert* Bone Screw implants and instruments for small bones are conveniently managed in four separate trays with lids. The trays are available individually or as a set in a single case. The case and trays are molded polyetherimide for improved durability and reduced weight. The trays include: (1) a General Instrument Set, (2) a *Herbert* Set with screws and improved instruments, including the Huene Alignment Guide; (3) a *Herbert/Whipple* Set with cannulated screws and specific instruments, and (4) a *Herbert Mini* Set with screws and specific instruments. Instruments and screws are clearly labeled with silkscreened names and product numbers. Screw sizes are also indicated.



Herbert Bone Screw Systems General Instrument Set (1)

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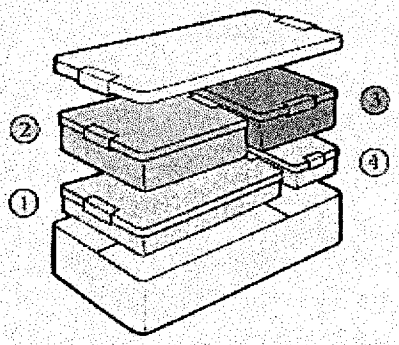
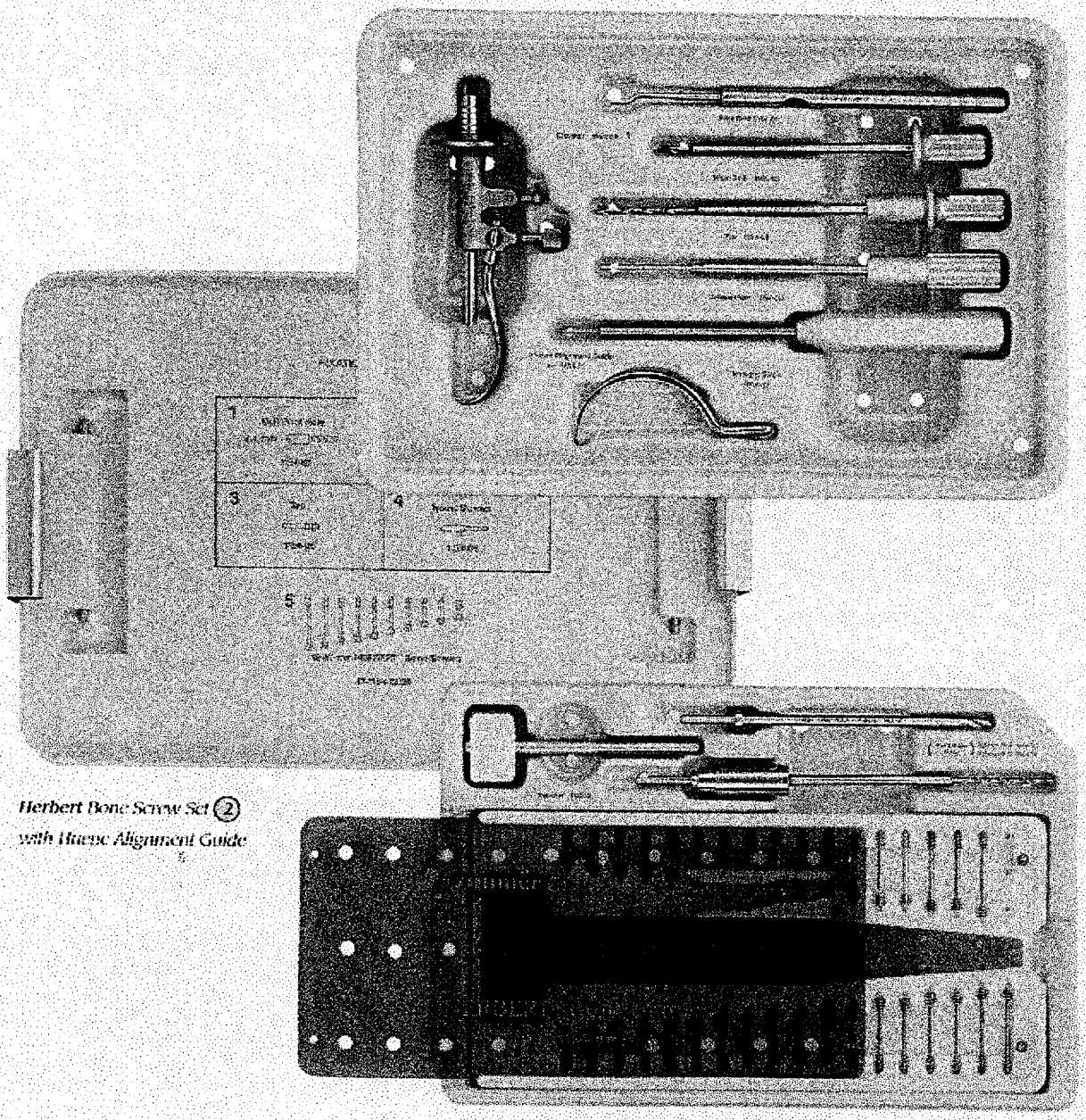
Individual screws or instruments can also be ordered separately. Screws are packaged sterile; instruments are packaged nonsterile.



Trays are available individually or together as a complete system set in a convenient case.



Herbert Bone Screw Set 2 with Huene Alignment Guide

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Herbert Bone Screw Systems Ordering Information

Herbert Bone Screw Implants

Screw Length mm	Herbert/Whipple	Herbert Mini	Herbert
10	-	1150-10	-
12	1152-12	1150-12	47-1154-12
14	1152-14	1150-14	47-1154-14
16	1152-16	1150-16	47-1154-16
18	1152-18	1150-18	47-1154-18
20	1152-20	-	47-1154-20
22	1152-22	-	47-1154-22
24	1152-24	-	47-1154-24
26	1152-26	-	47-1154-26
28	1152-28	-	47-1154-28
30	1152-30	-	47-1154-30

	Herbert/Whipple	Herbert Mini	Herbert
Leading Thread Diameter	3.0mm	2.5mm	3.0mm
Shaft Diameter	2.5mm	1.25mm	1.75mm
Trailing Thread Diameter	3.9mm	3.2mm	3.9mm

Herbert Bone Screw Systems General Instrument Set

Cat. No.	Description	Qty in Set
1154-79	**Herbert Bone Screw General Instrument Set (Set includes the following instrumentation and sterilization case)**	
1152-62	Free-Hand Guide Insert Screw	1
1154-08	Dissector	1
1154-40	Double-Ended Retractor	2
1154-78	Small Retractor	1
1154-92	Free-Hand Guide	1
2446-07	Bone-Holding Forceps	1
2446-39	Sharp Hook	1
2910-02	Periosteal Elevator, 1/4-inch	1
3027	Soft Tissue Retractor	1
3088-20	Hohmann Retractor, 6mm	1
3088-21	Hohmann Retractor, 8mm	1
1156-95	Sterilization Case	1
OPTIONAL INSTRUMENT		
1154-77	Hand Rasp	1

Herbert Bone Screw Implants and Instrumentation

Cat. No.	Description	Qty in Set
1154-80	**Herbert Bone Screw Set (Set includes the following implants, instruments and sterilization case)**	
IMPLANTS		
47-1154-12	12mm	2
47-1154-14	14mm	2
47-1154-16	16mm	2
47-1154-18	18mm	2
47-1154-20	20mm	2
47-1154-22	22mm	2
47-1154-24	24mm	2
47-1154-26	26mm	2
47-1154-28	28mm	2
47-1154-30	30mm	2
INSTRUMENTATION		
1154-01	Pilot Drill, 2.4mm diameter	1
1154-02	Main Drill, 2.6mm diameter	1
1154-05	Tap	1
1154-06	Hex Screwdriver	1
1154-09	Elevator	1
1154-10	Trephine	1
1154-11	Humic Alignment Guide (includes Guide Barrel and Scaphoid Blade)	1
1154-19	Straight Blade	1
1154-70	Power Pilot Drill, 3.2mm	1
1154-71	Power Main Drill, 2.6mm	1
1154-95	Sterilization Case	1
1154-81	**Herbert Bone Screw Instrumentation Set (Set includes instrumentation and sterilization case only; no implants)**	

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Herbert/Whipple Bone Screw Cannulated Implants and Instrumentation

Cat. No.	Description	Qty. in Set
1152-90	**Herbert/Whipple Bone Screw Set (Set includes the following implants, instrumentation and case components)**	
IMPLANTS		
1152-12	Cannulated Screw, 12mm	2
1152-14	Cannulated Screw, 14mm	2
1152-16	Cannulated Screw, 16mm	2
1152-18	Cannulated Screw, 18mm	2
1152-20	Cannulated Screw, 20mm	2
1152-22	Cannulated Screw, 22mm	2
1152-24	Cannulated Screw, 24mm	2
1152-26	Cannulated Screw, 26mm	2
1152-28	Cannulated Screw, 28mm	2
1152-30	Cannulated Screw, 30mm	2
INSTRUMENTATION		
1152-01	Cannulated Screwdriver	1
1152-02	Cannulated Cortical Broach	1
1152-03	Cannulated Step Drill	1
1152-04	Depth Gauge	1
1152-05	Cannulated Tap	1
1152-06	Alignment Guide	1
1152-50	Guide Wires, 1mm diameter	5
1152-55	Free-Hand Depth Gauge	1
1162-60	Sleeves	2
1152-70	Cannula	1
1152-71	Obturator	1
1154-10	Trephine	1
1154-90	Modular Handle	1
2313-11	Screw Forceps	1
1152-95	Sterilization Case	1
1152-93	**Herbert/Whipple Bone Screw Instrumentation Set (Set includes instrumentation and sterilization case only; no implants)**	
OPTIONAL CLEANING INSTRUMENTS		
1152-08	Cannula Cleaner	
1152-09	Pencil End Brush	
1152-11	Twisted Wire Brush	

Herbert Mini Bone Screw Implants and Instrumentation

Cat. No.	Description	Qty. in Set
1150-90	**Herbert Mini Bone Screw Set (Set includes the following implants, instrumentation and sterilization case)**	
IMPLANTS		
1150-10	10mm	2
1150-12	12mm	2
1150-14	14mm	2
1150-16	16mm	2
1150-18	18mm	2
INSTRUMENTATION		
1150-03	Pilot Drill, 2.3mm diameter	1
1150-04	Main Drill, 1.6mm diameter	1
1150-05	Tap	1
1150-06	Screwdriver	1
1150-07	Trephine	1
1150-51	Free-Hand Guide	1
1150-95	Sterilization Case	1
1150-91	**Herbert Mini Bone Screw System Instrumentation Set (Set includes instrumentation and sterilization case only; no implants)**	

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Herbert Bone Screw Systems Ordering Information

Herbert Bone Screw Sterilization Cases

Cat No.	Description
1152-95	Herbert/Whipple Bone Screw Screw/Instrument Sterilization Case
CASE COMPONENTS	
1152-96	Instrument Base
1152-96-01	Instrument Middle Tray
1152-97	Instrument Top Tray
1152-97-01	Instrument Screw Tray
1152-97-02	Instrument Screw Tray Lid
1152-98	Instrument Lid

1150-95	Herbert Mini Bone Screw Screw/Instrument Sterilization Case
CASE COMPONENTS	
1150-96	Instrument Base
1150-96-01	Screw Tray
1150-96-02	Screw Tray Lid
1150-97	Instrument Lid

1154-95	Herbert Bone Screw Screw/Instrument Sterilization Case
CASE COMPONENTS	
1154-96	Instrument Base
1154-97	Instrument Top Tray
1154-97-01	Instrument Screw Tray
1154-97-02	Instrument Screw Tray Lid
1154-98	Instrument Lid

1156-95	Herbert Bone Screw General Instrument Sterilization Case
CASE COMPONENTS	
1156-96	General Instrument Base
1156-96-01	General Instrument Base Mat
1156-97	General Instrument Tray
1156-98	General Instrument Lid

1156-85	Herbert Bone Screw Sterilization Cases Holder (This case holds all four of the sterilization cases above)
CASE COMPONENTS	
1156-86	Herbert Bone Screw Case Holder Base
1156-87	Herbert Bone Screw Case Holder Lid

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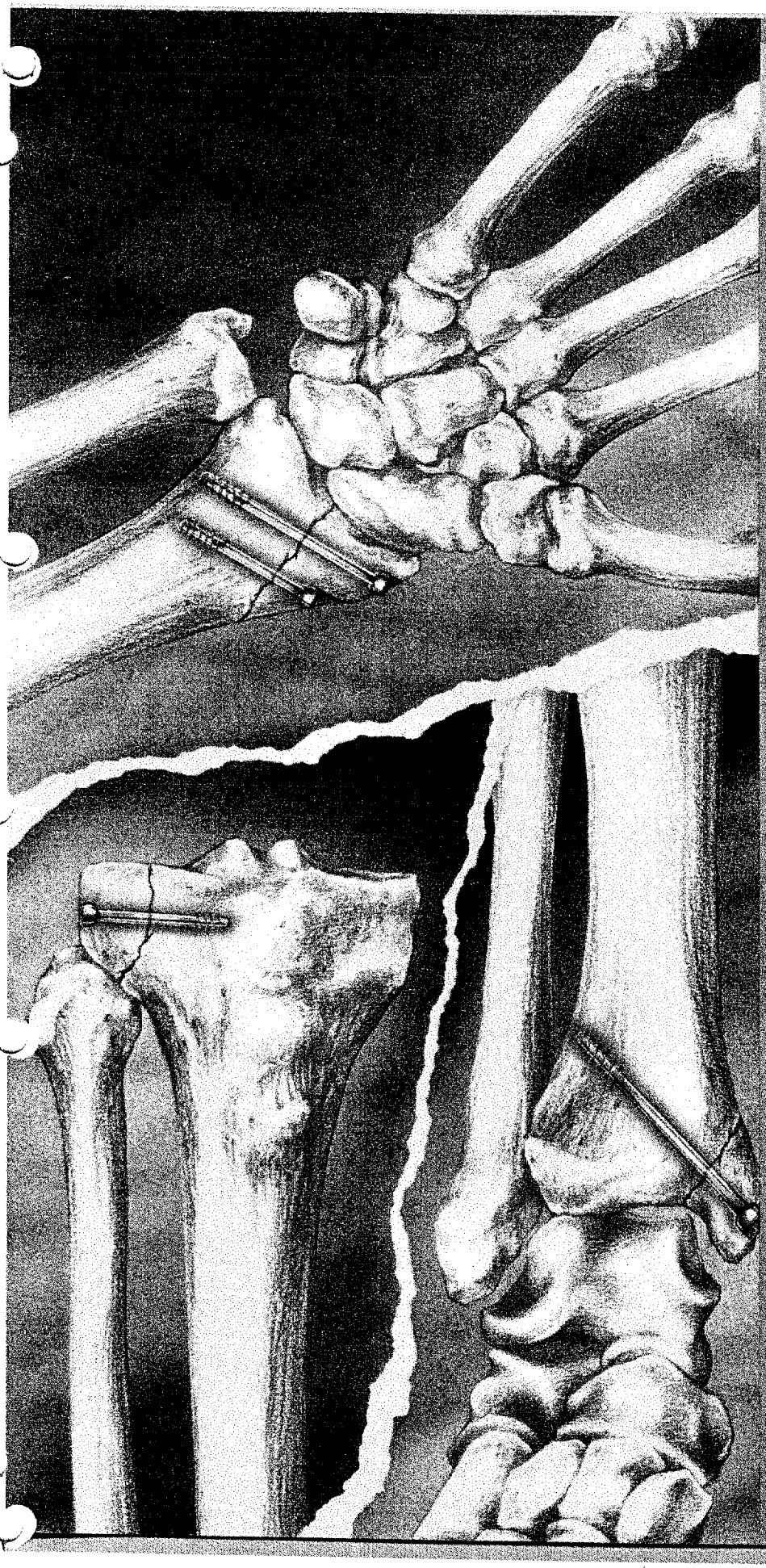

FRACTURE MANAGEMENT

Mini Magna-Fx® Cannulated Screw Fixation System

Precise Reduction and Fixation of Small Bone Fragments

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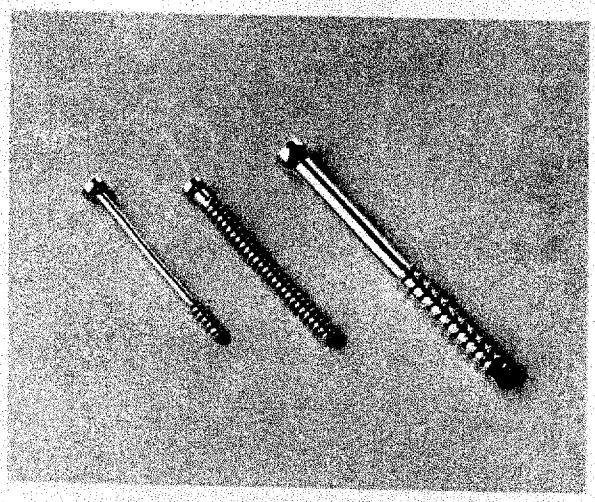
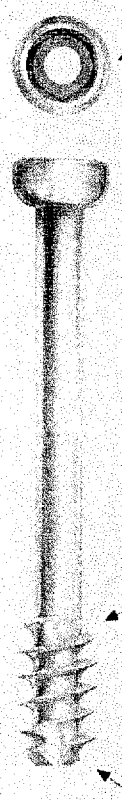
Mini Magna-Fx Cannulated Screw Fixation System

Employing the Proven Features of Magna-Fx





Optimal Effectiveness, Minimal Invasiveness

Designed to provide optimal fixation with the minimal invasiveness of a small-diameter cannulated screw. The 4.0mm and 5.0mm *Mini Magna-Fx* Cannulated Screws are guided into correct position over Guide Wires.

These small cannulated screws allow for efficient procedures that require less OR time, and cause less trauma for the patient than larger-diameter screws.

Strength Through Material

The use of 22-13-5 stainless steel makes the *Mini Magna-Fx* Screw stonger than 316L stainless steel screws, while at the same time allowing it to have a minimal major diameter and deeper threads for greater purchase. The strength of the screw enables it to be self-tapping, have reverse-cutting threads for facilitation of removal, and allows the use of a larger 3.5mm hex for a positive drive.

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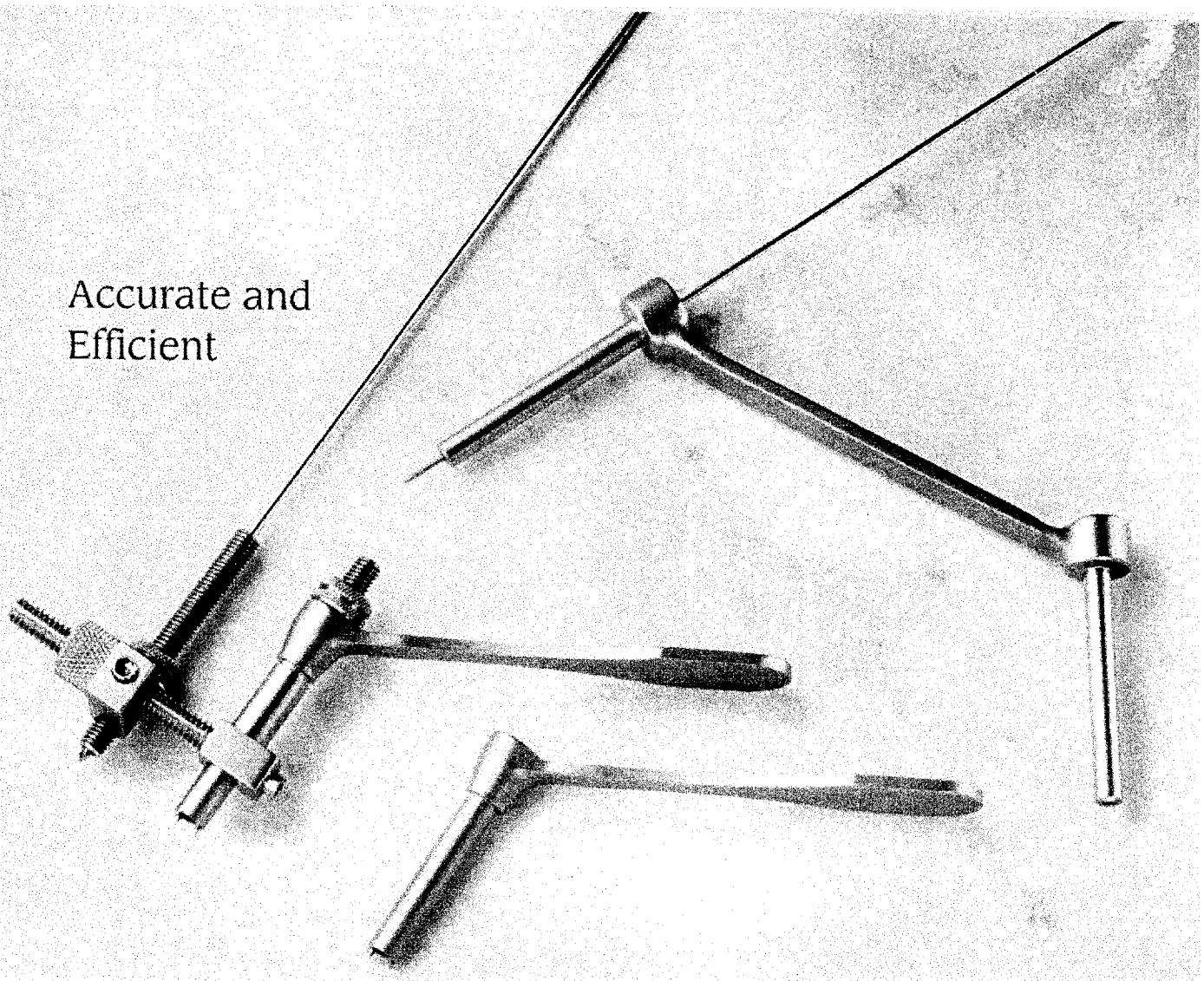
Accurate and Efficient



Precise Reduction, Fixation

The addition of 4.0mm and 5.0mm fully and partially threaded cancellous screws completes the *Magna-Fx* System and allows for precise reduction and fixation of small bone fragments.

Indications for *Mini Magna-Fx* Screw

- Fractures of the medial malleolus, distal fibula, distal tibia, patella, talus, calcaneus, and small bones of the feet
- Arthrodesis of the carpals, tarsals, and phalanges
- Intracondylar fractures of the distal humerus
- Fixation of bone prominence for the lateral end of the clavicle and the coracoid process
- Reduction and fixation of small bone fragments
- Ligament fixation when used with a washer

Unique Instrumentation

The *Mini Magna-Fx* System utilizes positive stops on the Drill Sleeve to prevent overdrilling and introduces an optional Parallel Placement Jig, which employs the following features:

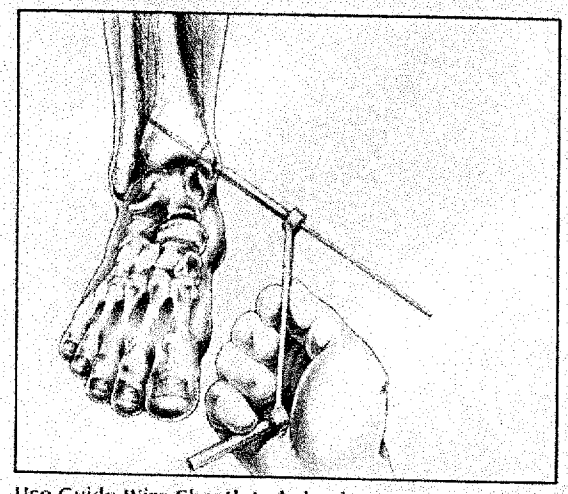
- Locates a screw parallel to original screw
- Jig rotates around original screw
- Positions second screw on a radius between 20mm and 70mm from original screw

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

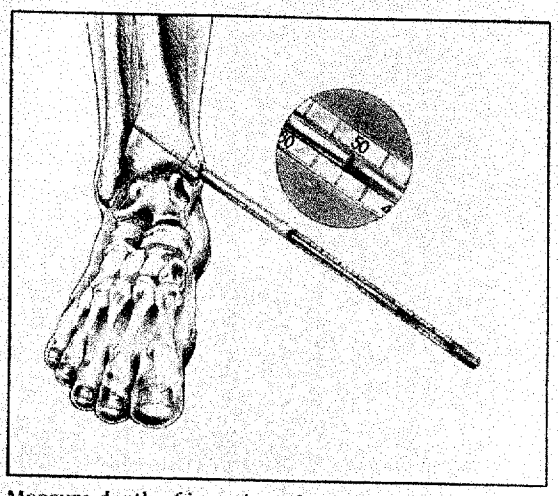
Surgical Technique

① PLACE GUIDE WIRE



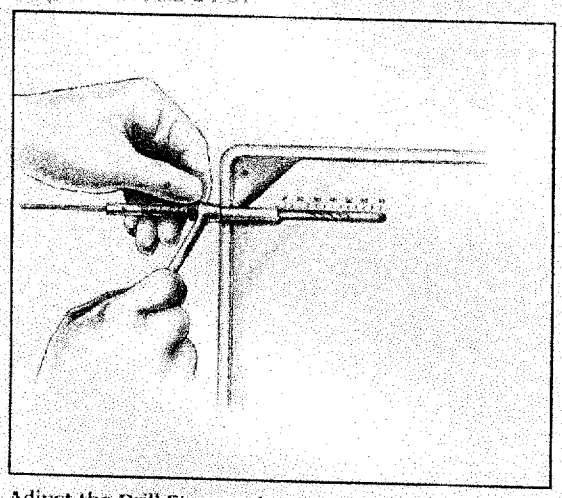
Use Guide Wire Sheath to help place one or more Guide Wires.

② MEASURE DEPTH



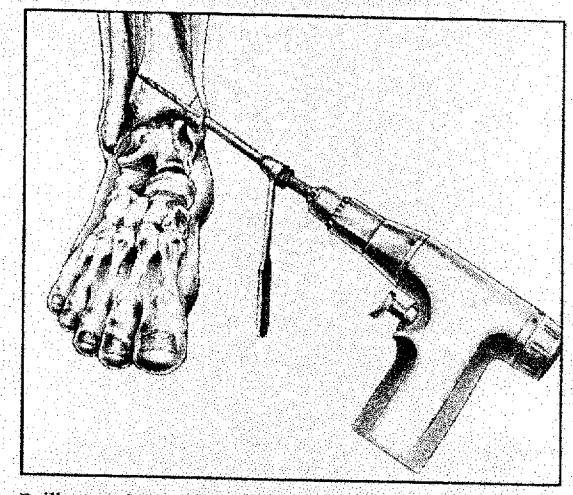
Measure depth of insertion of Guide Wire with Depth Gauge.

③ ADJUST DRILL STOP



Adjust the Drill Stop on the Insert Drill Sleeve to get the desired drill depth.

④ DRILL



Drill over the Guide Wire to the preset drill depth. **NOTE:** The *Mini Magna-Fx* Screws have self-tapping threads. **However, for dense bone tapping is recommended prior to screw insertion.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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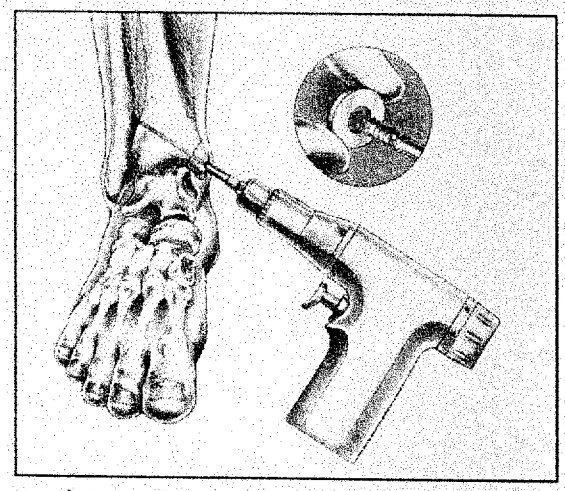
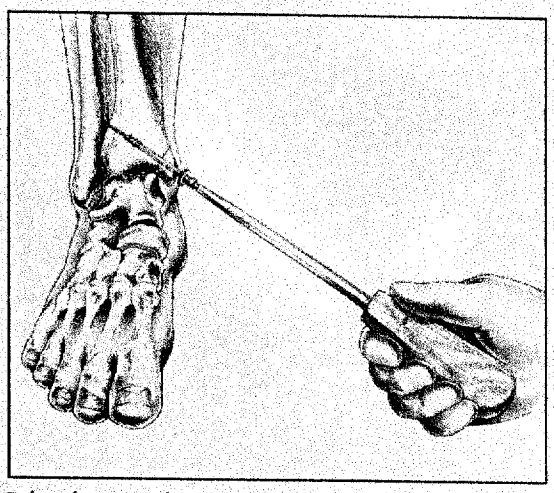
⑤ COUNTERSINK



Use the Cannulated Countersink to countersink the hole, allowing accommodation of the screw head. If a washer is to be used, skip this step and place the washer on the screw prior to insertion (see inset).

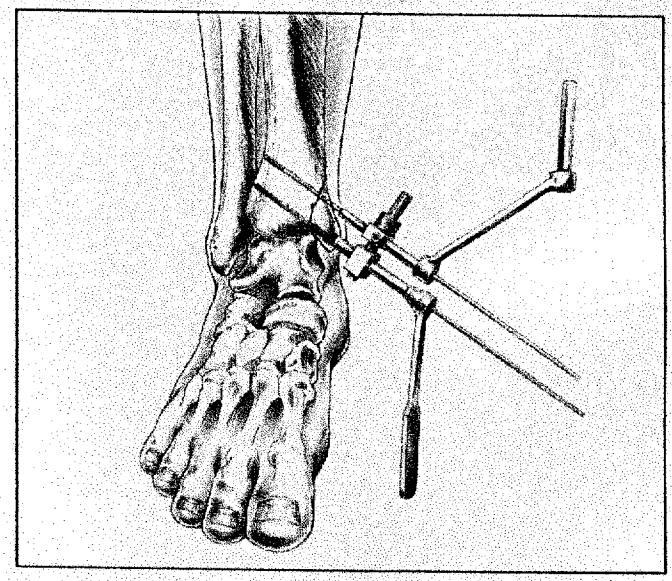
⑥ INSERT SCREW



Drive the cannulated screw over the Guide Wire using the Cannulated Screwdriver. Remove the Guide Wire after the screw is seated.

Optional

USE OF PARALLEL PLACEMENT JIG*



After placing the Guide Wire in the bone, use the Free-Hand Drill Guide with the Parallel Placement Jig positioned at the distance where the parallel hole is desired. Use the Guide Wire Sheath to place the Guide Wire parallel to the initial Guide Wire.

* U.S. Patent Pending

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2015-7972; Released by CDRH on 03/11/2016

Ordering Information

4.0mm Cannulated Screws

Fully Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-40-12	12mm	1142-40-28	28mm	1142-40-44	44mm
1142-40-16	16mm	1142-40-32	32mm	1142-40-48	48mm
1142-40-20	20mm	1142-40-36	36mm	1142-40-55	55mm
1142-40-24	24mm	1142-40-40	40mm	1142-40-65	65mm

Partially Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-41-24	24mm	1142-41-36	36mm	1142-41-48	48mm
1142-41-26	26mm	1142-41-38	38mm	1142-41-50	50mm
1142-41-28	28mm	1142-41-40	40mm	1142-41-55	55mm
1142-41-30	30mm	1142-41-42	42mm	1142-41-60	60mm
1142-41-32	32mm	1142-41-44	44mm	1142-41-65	65mm
1142-41-34	34mm	1142-41-46	46mm	1142-41-70	70mm

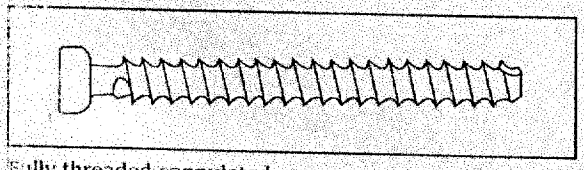
5.0mm Cannulated Screws

Fully Threaded *Mini Magna-Fx* Cannulated Screws

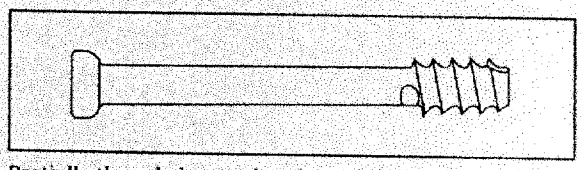
Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-50-12	12mm	1142-50-28	28mm	1142-50-44	44mm
1142-50-16	16mm	1142-50-32	32mm	1142-50-48	48mm
1142-50-20	20mm	1142-50-36	36mm	1142-50-55	55mm
1142-50-24	24mm	1142-50-40	40mm	1142-50-65	65mm

Partially Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-51-24	24mm	1142-51-36	36mm	1142-51-48	48mm
1142-51-26	26mm	1142-51-38	38mm	1142-51-50	50mm
1142-51-28	28mm	1142-51-40	40mm	1142-51-55	55mm
1142-51-30	30mm	1142-51-42	42mm	1142-51-60	60mm
1142-51-32	32mm	1142-51-44	44mm	1142-51-65	65mm
1142-51-34	34mm	1142-51-46	46mm	1142-51-70	70mm



Fully threaded cannulated screw



Partially threaded cannulated screw

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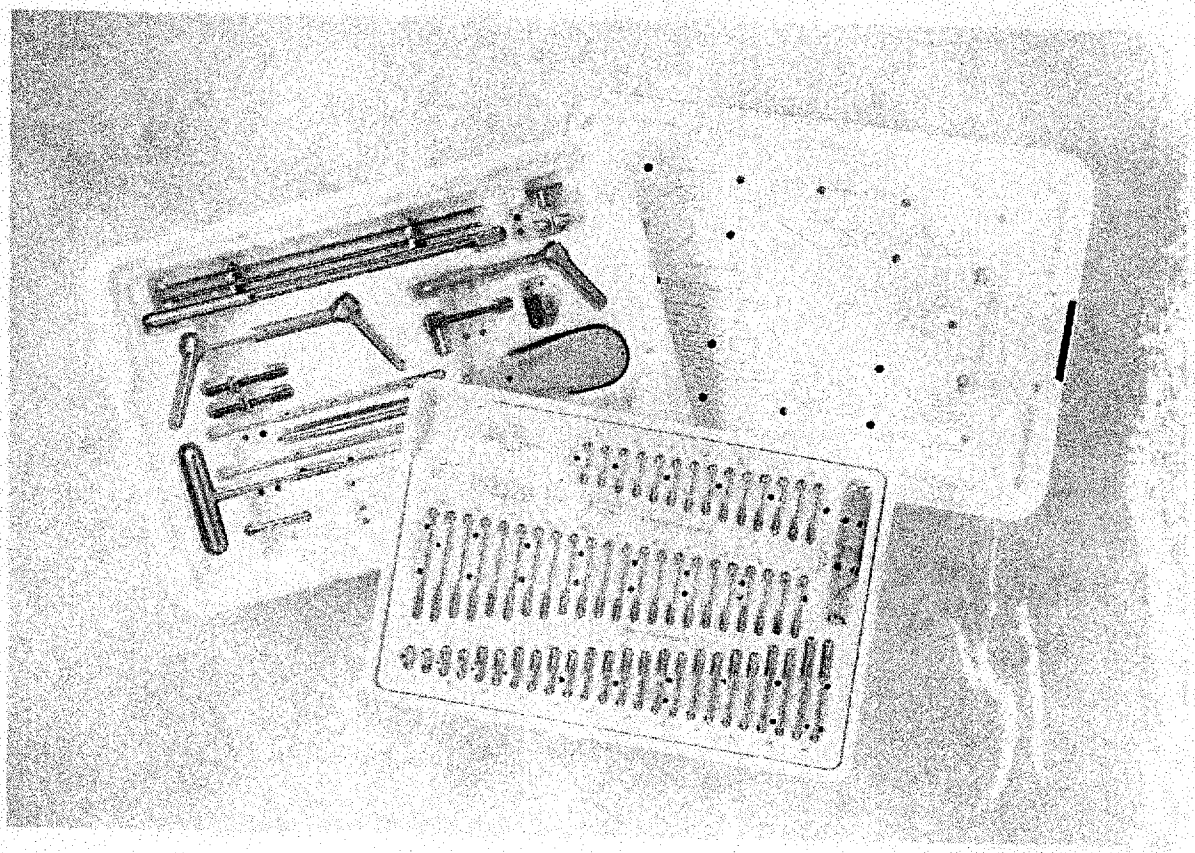

Instrumentation

Cat. No.	Description	Qty in Set
1142	*Mini Magna-Fx* Cannulated Screw Instrument Set (set includes the following instruments & sterilization case components)	—
1142-01-17	Guide Wire, Partially Thd, 1.7mm	6
1142-01-25	Guide Wire, Partially Thd, 2.5mm	6
1142-02	Cannulated Screwdriver, 3.5mm	1
1142-11-27	Cannulated Drill, 2.7mm	1
1142-11-35	Cannulated Drill, 3.5mm	1
1142-12	Free-Hand Drill Guide	1
1142-13	Parallel Placement Jig	1
1142-14	Depth Gauge	1
1142-15	Screw Extractor	1
1142-16-27	Insert Drill Sleeve, 2.7mm	1
1142-16-35	Insert Drill Sleeve, 3.5mm	1
1142-17	Cannulated Countersink	1
1142-18	Washer	6
1142-19	Guide Wire Sheath	1

Cat. No.	Description	Qty in Set
2313-11	Screw Forceps	1
1142-80	*Mini Magna-Fx* Implant/Instrument Set Case (includes the following case components)	—
1142-82	Implant/Instrument Case Base	1
1142-86	Implant/Instrument Case Lid	1
1142-81	Implant Case (includes the following implant case components)	
1142-83	Implant Case Base	1
1142-84	Implant Case Tray	1
1142-85	Implant Case Lid	1
Optional Instruments (not included in set)		
1142-20-40	Cannulated Tap, 4.0mm	1
1142-20-50	Cannulated Tap, 5.0mm	1
Implants Only		
1142-00-01	4.0mm and 5.0mm Screws (40 ea.)	80
1142-00-02	4.0mm Screws	40
1142-00-03	5.0mm Screws	40

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mini Magna-Fx® Cannulated Screw Fixation System

Issued August 1993

DESCRIPTION

The *Mini Magna-Fx* Cannulated Bone Screw is designed to provide secure fixation of various fractures (see INDICATIONS FOR USE). The screw is available in two diameter sizes, 4.0 mm and 5.0 mm, with a fully or partially threaded design. The 4.0 mm and 5.0 mm screws are cannulated for use over a 1.7 mm and 2.5 mm guide wire, respectively. Screws come in lengths from 12 mm to 70 mm. A self-tapping tip is an additional screw feature. Washers are available for use to prevent the screw head from pulling through the cortex in cases where the cortical bone is soft or thin. The screws are made from 22-13-5 stainless steel. Special cannulated instruments are also available for insertion of the screws.

INDICATIONS FOR USE

Indications for the device include fractures of the: medial malleolus, distal tibia, distal radius, calcaneus, talus, patella, pelvis, as well as for fixation of bone prominences and supracondylar fractures of the distal humerus in children. The screw can also be used through the cancellous screw hole of certain *ECT*™ bone plates.

CONTRAINDICATIONS

Contraindications to usage of this device include: sepsis, preexisting joint disease, arthritis, osteoporosis or inadequate bone stock, long delay after injury, advanced age, chronic renal failure, foreign body sensitivity, and patient inability to follow imposed restrictions on activities due to mental or neurological illness.

WARNINGS

Preoperative and operating procedures, including knowledge of proper technique, good reduction, and proper selection and placement of the implant, are important considerations in the successful utilization of the *Mini Magna-Fx* Screw. Accurate placement of the guide wires, drilling, countersinking, tapping, and screw position should be verified at surgery by multiple views using image intensification fluoroscopy. When using the guide wire sheath (1142-19), pins should be directed into the bone with caution and utilizing fluoroscopic control.

The threads of the screw must not lie across the fracture site as this not only reduces screw fatigue life, but has a tendency to distract the fracture fragments.

Detailed instructions on the use and limitations of this device must be given to the patient. If limited or full weight-bearing is recommended prior to firm bony union, the patient must be warned that bending or breakage of the device and loss of fixation are complications which can occur. These complications may necessitate surgical revision. Weight-bearing to tolerance can be undertaken under strict patient supervision whenever the surgeon is confident of the reduction and when satisfactory impaction and rigid fixation are achieved. Use of a [illegible] er should be continued until the fracture is firmly united.

Stability and durability of fixation are compromised by loss of cortical bone support by comminution, nonparallel screws not engaging subchondral bone and osteoporosis. Any of these conditions would increase patient risk during unprotected weight-bearing.

PRECAUTIONS

A temporary internal fixation device must never be reused. If metal screws, wire, bands, or other metallic devices are used together with *Mini Magna-Fx* Screws, all such devices must be manufactured from a compatible alloy. These include 22-13-5 and 316L stainless steels per ASTM specifications F-138/139 and F1314 with respect to chemical composition and metallurgical state to avert the possibility of galvanic corrosion or other metallic reactions.

Internal fixation devices are designed to stabilize the fracture site during the normal healing process. After healing occurs, these devices serve no functional purpose and, therefore, should be removed. In most cases, removal is indicated because these implants are not intended to transfer support forces developed during normal activities. If the device is not removed, any of the following complications may occur: corrosion, with localized tissue reaction or pain; migration, resulting in injury to soft tissue, visceral organs, or joints; risk of additional injury from postoperative trauma, breakage, which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device; possible increased risk of infection; bone loss due to stress shielding; and in children, the longitudinal growth of long bones where the fracture and the implant are near the growth plate may be significantly retarded (i.e. proximal tibia).

Any decision to remove the device must take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid refracture.

ADVERSE EFFECTS

Screw breakage can occur. This can happen due to fatigue failure as a result of prolonged loading upon the screw or due to excessive forces during insertion or removal.

Other possible adverse effects include: chondrolysis resulting from screw penetration into the subchondral bone of the joint; screw penetration resulting in pain and erosive joint changes; and screw migration into joint area.

In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. A variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants have been known to cause cancer and other adverse body reactions. In addition, any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; patients suffering from this disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign material in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.[1] While formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys.[2] Titanium and its alloys (such as *Titanium*® Ti-6Al-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

STERILITY

The *Mini Magna-Fx* Screw is provided sterile by prior exposure to 2.5 Mrad gamma irradiation. If required, the unused product can be resterilized using accepted procedures for steam autoclaving or ethylene oxide. No aeration is needed for solid metal items.

HOW SUPPLIED

Please refer to the *Mini Magna-Fx* Cannulated Screw Fixation System brochure/surgical technique for a complete listing of implant components and instrumentation.

Note:

1. On fully threaded 4.0 mm and 5.0 mm screws, the thread length is also the screw length.

REFERENCES

1. American Society for Testing and Materials, ASTM Committee F-4, Symposium on Biocompatibility of Particulate Implant Materials, October 31, 1990.
2. Fisher AA. *Contact Dermatitis*. 3rd Ed., Lea and Febiger, 1986;338-367.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

If more than two years have elapsed since revision, contact the manufacturer for current information.

zimmer

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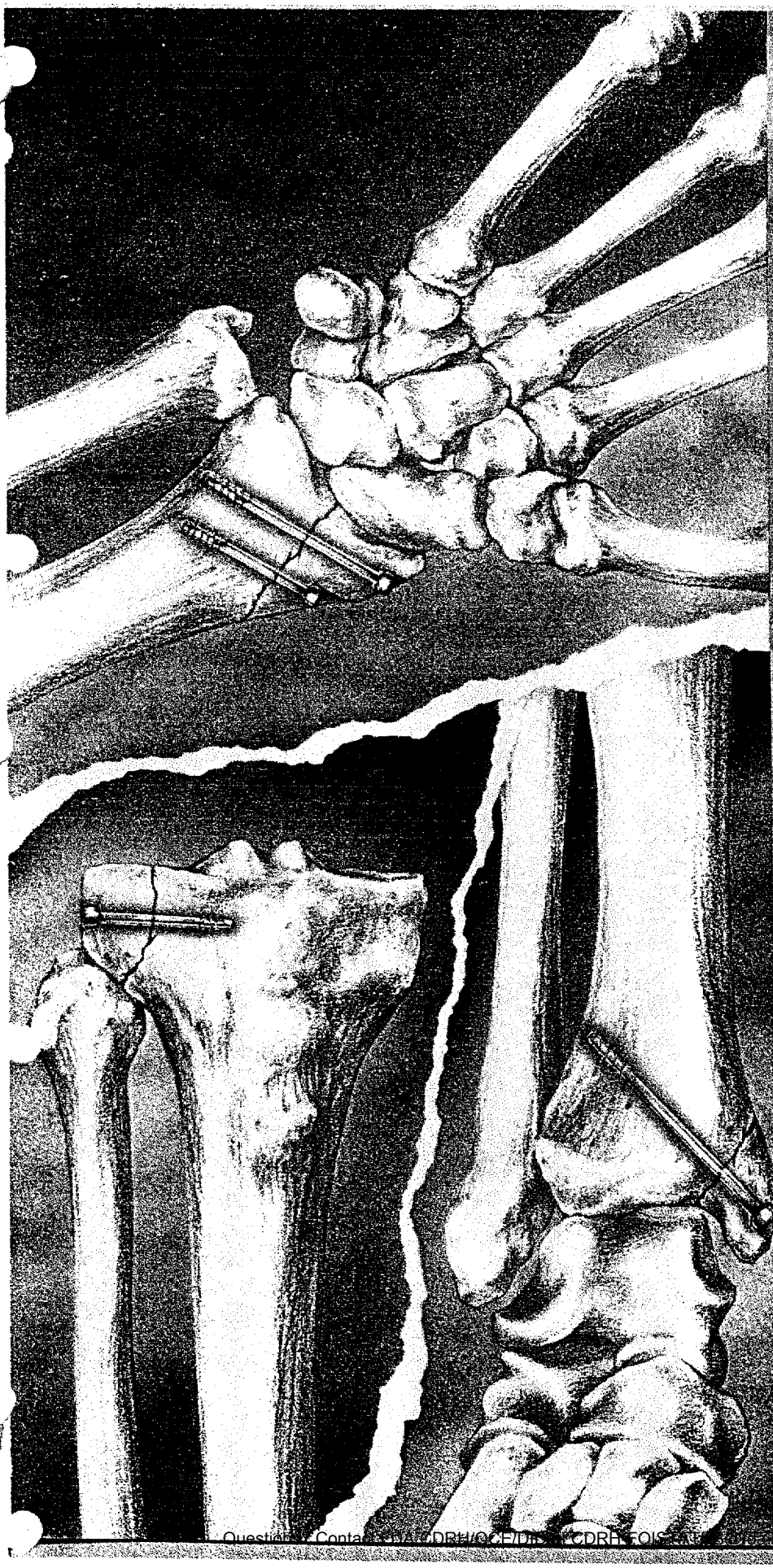

FRACTURE MANAGEMENT

Mini Magna-Fx® Cannulated Screw Fixation System

Precise Reduction and Fixation of Small Bone Fragments

Questions? Contact FDA/CDRH/OCE/DIS CDRH-FOIS

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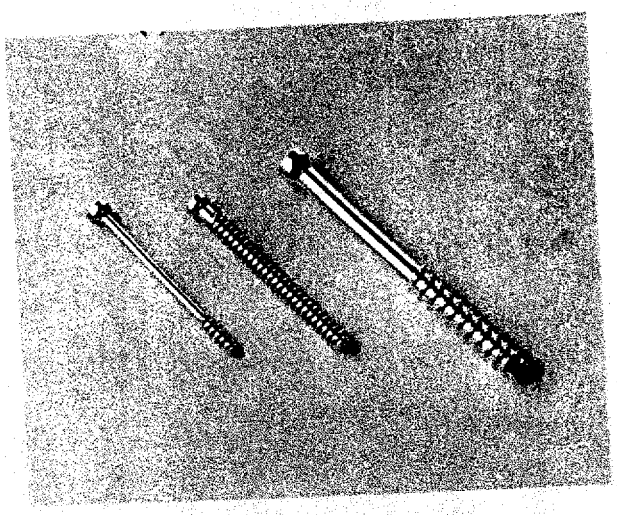
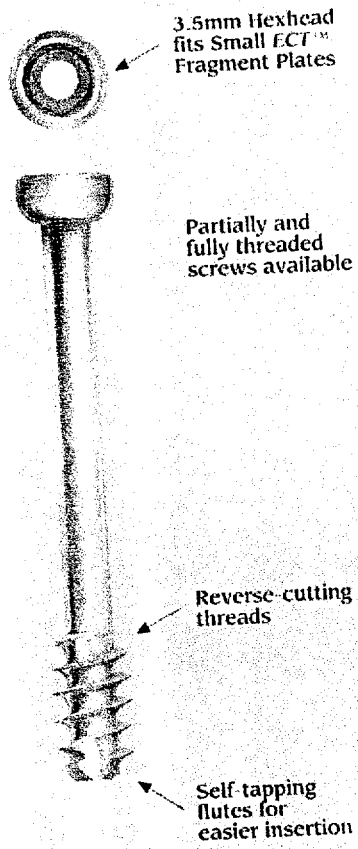
Mini Magna-Fx Cannulated Screw Fixation System

Employing the Proven Features of Magna-Fx





Optimal Effectiveness, Minimal Invasiveness

Designed to provide optimal fixation with the minimal invasiveness of a small-diameter cannulated screw. The 4.0mm and 5.0mm *Mini Magna-Fx* Cannulated Screws are guided into correct position over Guide Wires.

These small cannulated screws allow for efficient procedures that require less OR time, and cause less trauma for the patient than larger-diameter screws.

Strength Through Material

The use of 22-13-5 stainless steel makes the *Mini Magna-Fx* Screw stonger than 316L stainless steel screws, while at the same time allowing it to have a minimal major diameter and deeper threads for greater purchase. The strength of the screw enables it to be self-tapping, have reverse-cutting threads for facilitation of removal, and allows the use of a larger 3.5mm hex for a positive drive.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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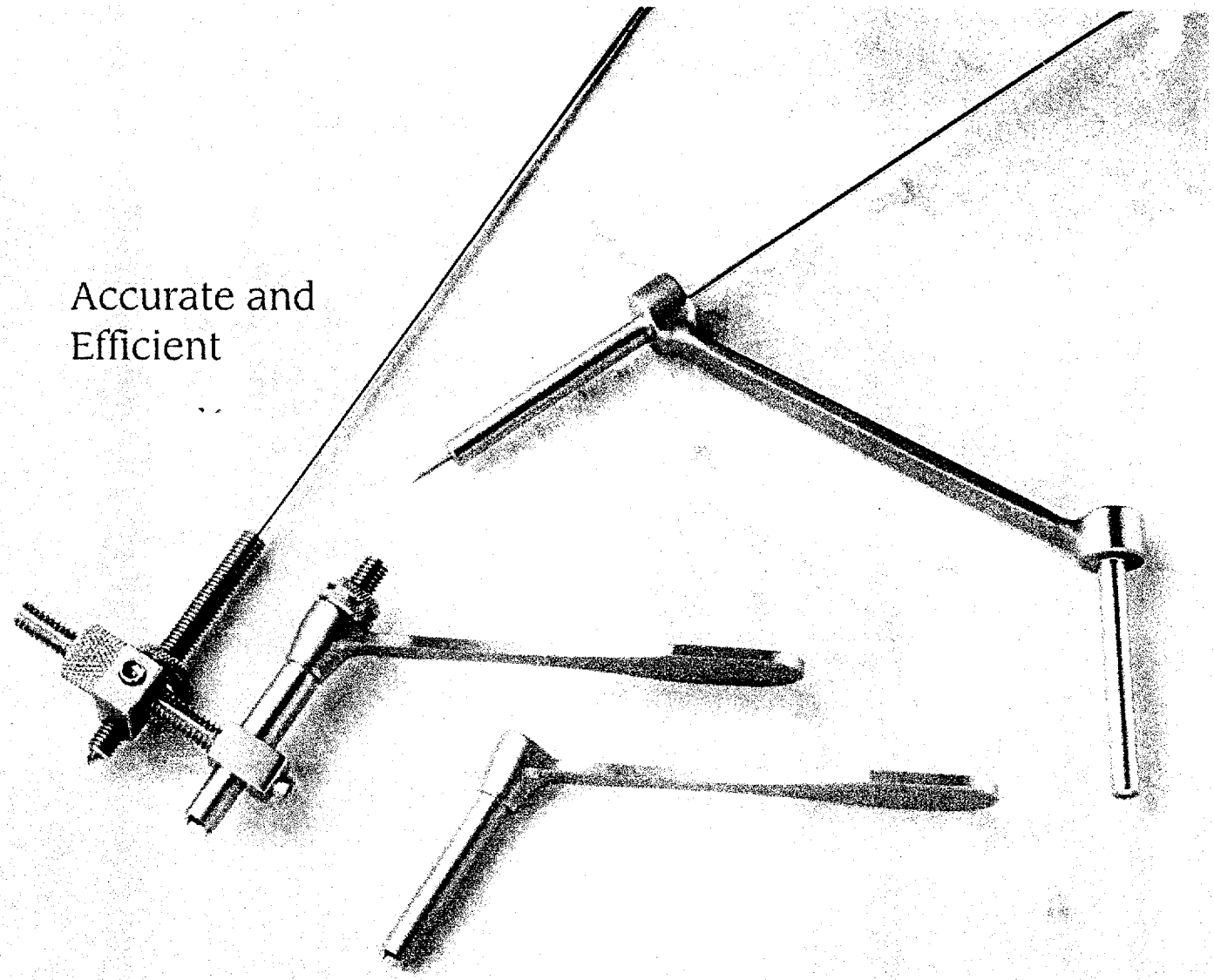
Accurate and Efficient



Precise Reduction, Fixation

The addition of 4.0mm and 5.0mm fully and partially threaded cancellous screws completes the *Magna-Fx* System and allows for precise reduction and fixation of small bone fragments.

Indications for *Mini Magna-Fx* Screw

- Fractures of the medial malleolus, distal fibula, distal tibia, patella, talus, calcaneus, and small bones of the feet
- Arthrodesis of the carpals, tarsals, and phalanges
- Intracondylar fractures of the distal humerus
- Fixation of bone prominence for the lateral end of the clavicle and the coracoid process
- Reduction and fixation of small bone fragments
- Ligament fixation when used with a washer

Unique Instrumentation

The *Mini Magna-Fx* System utilizes positive stops on the Drill Sleeve to prevent overdrilling and introduces an optional Parallel Placement Jig, which employs the following features:

- Locates a screw parallel to original screw
- Jig rotates around original screw
- Positions second screw on a radius between 20mm and 70mm from original screw

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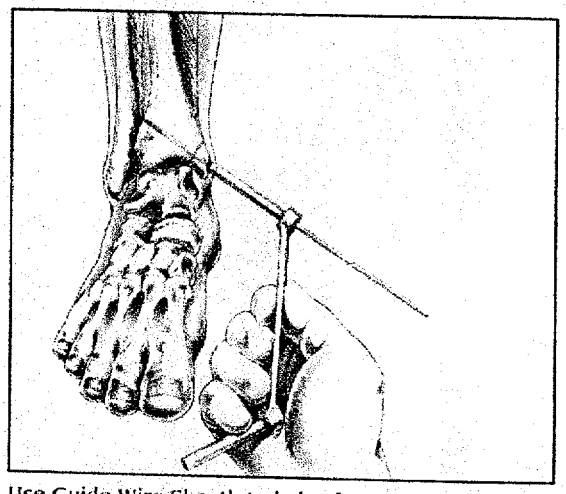
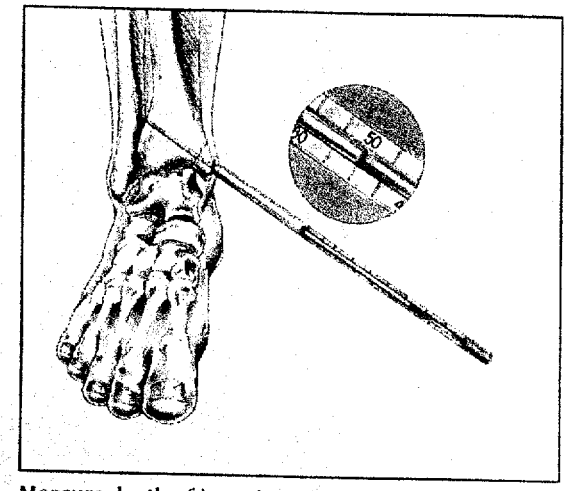
Surgical Technique

① PLACE GUIDE WIRE



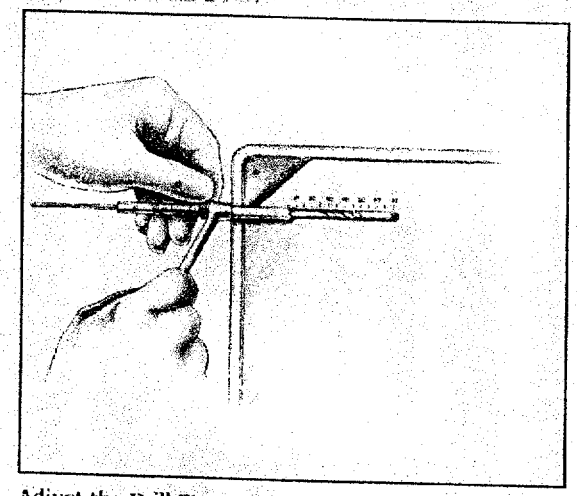
Use Guide Wire Sheath to help place one or more Guide Wires.

② MEASURE DEPTH



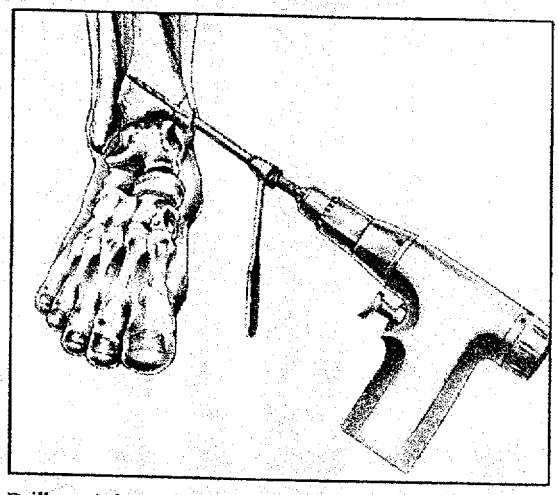
Measure depth of insertion of Guide Wire with Depth Gauge.

③ ADJUST DRILL STOP



Adjust the Drill Stop on the Insert Drill Sleeve to get the desired drill depth.

④ DRILL



Drill over the Guide Wire to the preset drill depth. **NOTE:** The *Mini Magna-Fx* Screws have self-tapping threads. **However, for dense bone tapping is recommended prior to screw insertion.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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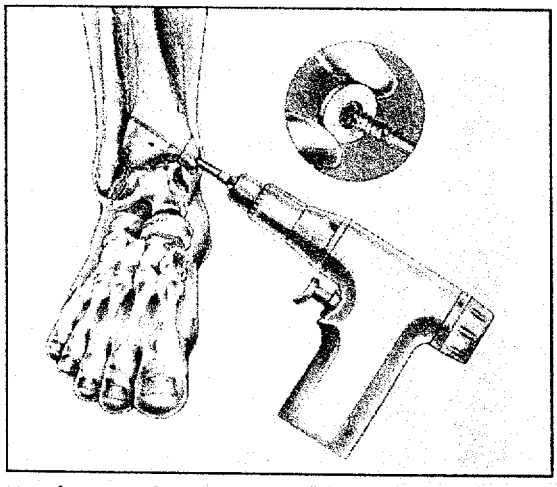
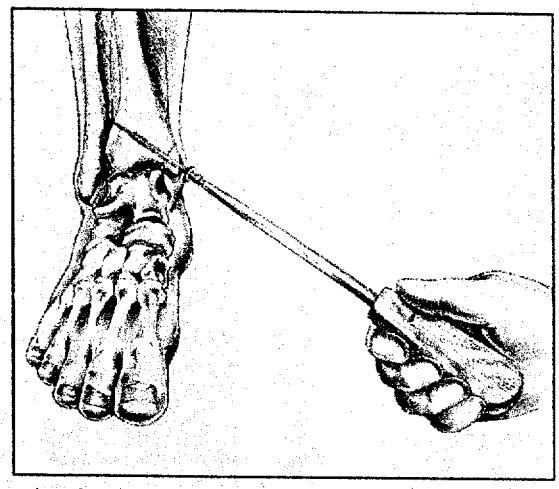
⑤ COUNTERSINK



Use the Cannulated Countersink to countersink the hole, allowing accommodation of the screw head. If a washer is to be used, skip this step and place the washer on the screw prior to insertion (see inset).

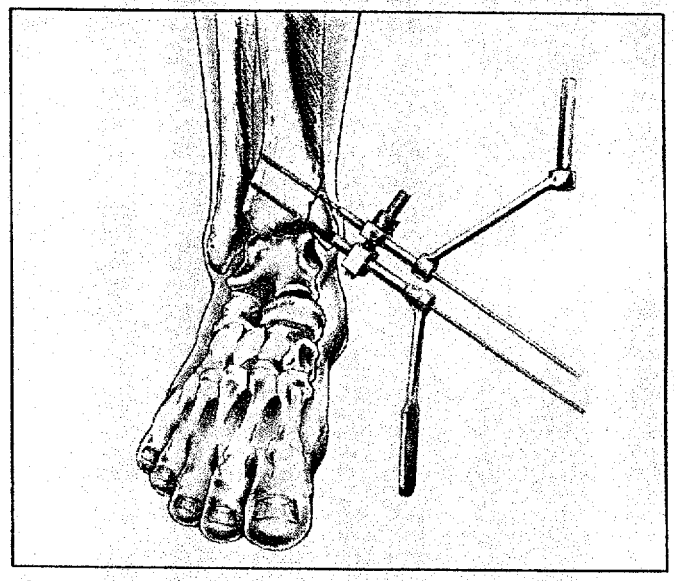
⑥ INSERT SCREW



Drive the cannulated screw over the Guide Wire using the Cannulated Screwdriver. Remove the Guide Wire after the screw is seated.

Optional

USE OF PARALLEL PLACEMENT JIG*



After placing the Guide Wire in the bone, use the Free-Hand Drill Guide with the Parallel Placement Jig positioned at the distance where the parallel hole is desired. Use the Guide Wire Sheath to place the Guide Wire parallel to the initial Guide Wire.

* U.S. Patent Pending

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Ordering Information

4.0mm Cannulated Screws

Fully Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-40-12	12mm	1142-40-28	28mm	1142-40-44	44mm
1142-40-16	16mm	1142-40-32	32mm	1142-40-48	48mm
1142-40-20	20mm	1142-40-36	36mm	1142-40-55	55mm
1142-40-24	24mm	1142-40-40	40mm	1142-40-65	65mm

Partially Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-41-24	24mm	1142-41-36	36mm	1142-41-48	48mm
1142-41-26	26mm	1142-41-38	38mm	1142-41-50	50mm
1142-41-28	28mm	1142-41-40	40mm	1142-41-55	55mm
1142-41-30	30mm	1142-41-42	42mm	1142-41-60	60mm
1142-41-32	32mm	1142-41-44	44mm	1142-41-65	65mm
1142-41-34	34mm	1142-41-46	46mm	1142-41-70	70mm

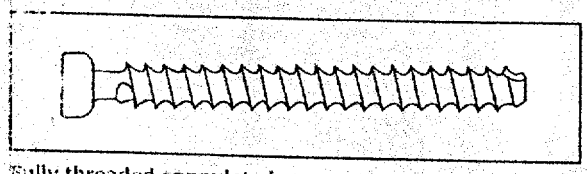
5.0mm Cannulated Screws

Fully Threaded *Mini Magna-Fx* Cannulated Screws

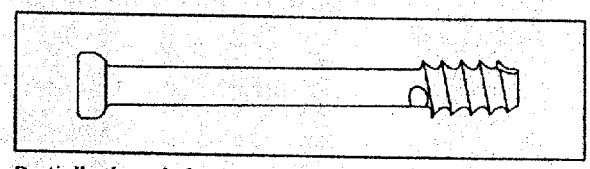
Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-50-12	12mm	1142-50-28	28mm	1142-50-44	44mm
1142-50-16	16mm	1142-50-32	32mm	1142-50-48	48mm
1142-50-20	20mm	1142-50-36	36mm	1142-50-55	55mm
1142-50-24	24mm	1142-50-40	40mm	1142-50-65	65mm

Partially Threaded *Mini Magna-Fx* Cannulated Screws

Cat. No.	Description	Cat. No.	Description	Cat. No.	Description
1142-51-24	24mm	1142-51-36	36mm	1142-51-48	48mm
1142-51-26	26mm	1142-51-38	38mm	1142-51-50	50mm
1142-51-28	28mm	1142-51-40	40mm	1142-51-55	55mm
1142-51-30	30mm	1142-51-42	42mm	1142-51-60	60mm
1142-51-32	32mm	1142-51-44	44mm	1142-51-65	65mm
1142-51-34	34mm	1142-51-46	46mm	1142-51-70	70mm



Fully threaded cannulated screw



Partially threaded cannulated screw

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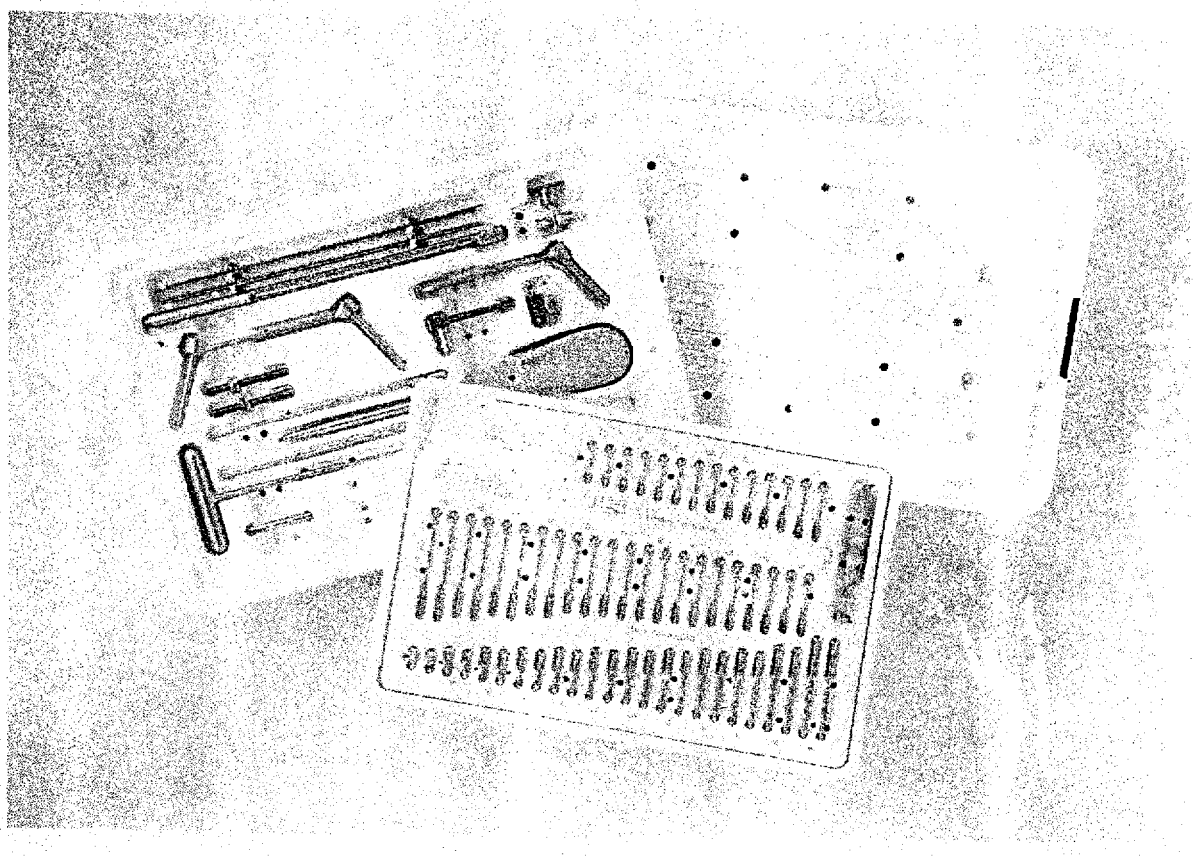

Instrumentation

Cat. No.	Description	Qty in Set
1142	*Mini Magna-Fx* Cannulated Screw Instrument Set (set includes the following instruments & sterilization case components)	—
1142-01-17	Guide Wire, Partially Thd, 1.7mm	6
1142-01-25	Guide Wire, Partially Thd, 2.5mm	6
1142-02	Cannulated Screwdriver, 3.5mm	1
1142-11-27	Cannulated Drill, 2.7mm	1
1142-11-35	Cannulated Drill, 3.5mm	1
1142-12	Free-Hand Drill Guide	1
1142-13	Parallel Placement Jig	1
1142-14	Depth Gauge	1
1142-15	Screw Extractor	1
1142-16-27	Insert Drill Sleeve, 2.7mm	1
1142-16-35	Insert Drill Sleeve, 3.5mm	1
1142-17	Cannulated Countersink	1
1142-18	Washer	6
1142-19	Guide Wire Sheath	1

Cat. No.	Description	Qty in Set
2313-11	Screw Forceps	1
1142-80	*Mini Magna-Fx* Implant/Instrument Set Case (includes the following case components)	—
1142-82	Implant/Instrument Case Base	1
1142-86	Implant/Instrument Case Lid	1
1142-81	Implant Case (includes the following implant case components)	
1142-83	Implant Case Base	1
1142-84	Implant Case Tray	1
1142-85	Implant Case Lid	1
Optional Instruments (not included in set)		
1142-20-40	Cannulated Tap, 4.0mm	1
1142-20-50	Cannulated Tap, 5.0mm	1
Implants Only		
1142-00-01	4.0mm and 5.0mm Screws (40 ea.)	80
1142-00-02	4.0mm Screws	40
1142-00-03	5.0mm Screws	40

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Mini Magna-Fx® Cannulated Screw Fixation System

Issued August 1993

DESCRIPTION

The *Mini Magna-Fx* Cannulated Bone Screw is designed to provide secure fixation of various fractures (see INDICATIONS FOR USE). The screw is available in two diameter sizes, 4.0 mm and 5.0 mm, with a fully or partially threaded design. The 4.0 mm and 5.0 mm screws are cannulated for use over a 1.7 mm and 2.5 mm guide wire, respectively. Screws come in lengths from 12 mm to 70 mm. A self-tapping tip is an additional screw feature. Washers are available for use to prevent the screw head from pulling through the cortex in cases where the cortical bone is soft or thin. The screws are made from 22-13-5 stainless steel. Special cannulated instruments are also available for insertion of the screws.

INDICATIONS FOR USE

Indications for the device include fractures of the: medial malleolus, distal tibia, distal radius, calcaneus, talus, patella, pelvis, as well as for fixation of bone prominences and supracondylar fractures of the distal humerus in children. The screw can also be used through the cancellous screw hole of certain *ECT*™ bone plates.

CONTRAINDICATIONS

Contraindications to usage of this device include: sepsis, preexisting joint disease, arthritis, osteoporosis or inadequate bone stock, long delay after injury, advanced age, chronic renal failure, foreign body sensitivity, and patient inability to follow imposed restrictions on activities due to mental or neurological illness.

WARNINGS

Preoperative and operating procedures, including knowledge of proper technique, good reduction, and proper selection and placement of the implant, are important considerations in the successful utilization of the *Mini Magna-Fx* Screw. Accurate placement of the guide wires, drilling, countersinking, tapping, and screw position should be verified at surgery by multiple views using image intensification fluoroscopy. When using the guide wire sheath (11-02-19), pins should be directed into the bone with caution and utilizing fluoroscopic control.

The threads of the screw must not lie across the fracture site as this not only reduces screw fatigue life, but has a tendency to distract the fracture fragments.

Detailed instructions on the use and limitations of this device must be given to the patient. If limited or full weight-bearing is recommended prior to firm bony union, the patient must be warned that bending or breakage of the device and loss of fixation are complications which can occur. These complications may necessitate surgical revision. Weight-bearing to tolerance can be undertaken under strict patient supervision whenever the surgeon is confident of the reduction and when satisfactory impaction and rigid fixation are achieved. Use of a [illegible] should be continued until the fracture is firmly united.

Stability and durability of fixation are compromised by loss of cortical bone support by comminution, nonparallel screws not engaging subchondral bone and osteoporosis. Any of these conditions would increase patient risk during unprotected weight-bearing.

PRECAUTIONS

A temporary internal fixation device must never be reused. If metal screws, wire, bands, or other metallic devices are used together with *Mini Magna-Fx* Screws, all such devices must be manufactured from a compatible alloy. These include 22-13-5 and 316L stainless steels per ASTM specifications F-138/139 and F1314 with respect to chemical composition and metallurgical state to avert the possibility of galvanic corrosion or other metallic reactions.

Internal fixation devices are designed to stabilize the fracture site during the normal healing process. After healing occurs, these devices serve no functional purpose and, therefore, should be removed. In most cases, removal is indicated because these implants are not intended to transfer support forces developed during normal activities. If the device is not removed, any of the following complications may occur: corrosion, with localized tissue reaction or pain; migration, resulting in injury to soft tissue, visceral organs, or joints; risk of additional injury from postoperative trauma, breakage, which could make removal impractical or difficult, pain, discomfort, or abnormal sensations which may occur due to the presence of the device; possible increased risk of infection; bone loss due to stress shielding, and in children, the longitudinal growth of long bones where the fracture and the implant are near the growth plate may be significantly retarded (i.e. proximal tibia).

Any decision to remove the device must take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid refracture.

ADVERSE EFFECTS

Screw breakage can occur. This can happen due to fatigue failure as a result of prolonged loading upon the screw or due to excessive forces during insertion or removal.

Other possible adverse effects include: chondrolysis resulting from screw penetration into the subchondral bone of the joint; screw penetration resulting in pain and erosive joint changes, and screw migration into joint area.

In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. A variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants have been known to cause cancer and other adverse body reactions. In addition, any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; patients suffering from this disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign material in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.[1] While formation of wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt chrome alloys.[2] Titanium and its alloys (such as *Tiunium*® Ti 6Al 4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

STERILITY

The *Mini Magna-Fx* Screw is provided sterile by prior exposure to 2.5 Mrad gamma irradiation. If required, the unused product can be resterilized using accepted procedures for steam autoclaving or ethylene oxide. No aeration is needed for solid metal items.

HOW SUPPLIED

Please refer to the *Mini Magna-Fx* Cannulated Screw Fixation System brochure/surgical technique for a complete listing of implant components and instrumentation.

Note:

1. On fully threaded 4.0 mm and 5.0 mm screws, the thread length is also the screw length.

REFERENCES

1. American Society for Testing and Materials, ASTM Committee F-4, Symposium on Biocompatibility of Particulate Implant Materials, October 31, 1990.
2. Fisher AA. *Contact Dermatitis*. 3rd Ed., Lea and Febiger, 1986;338-367.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

If more than two years have elapsed since revision, contact the manufacturer for current information.

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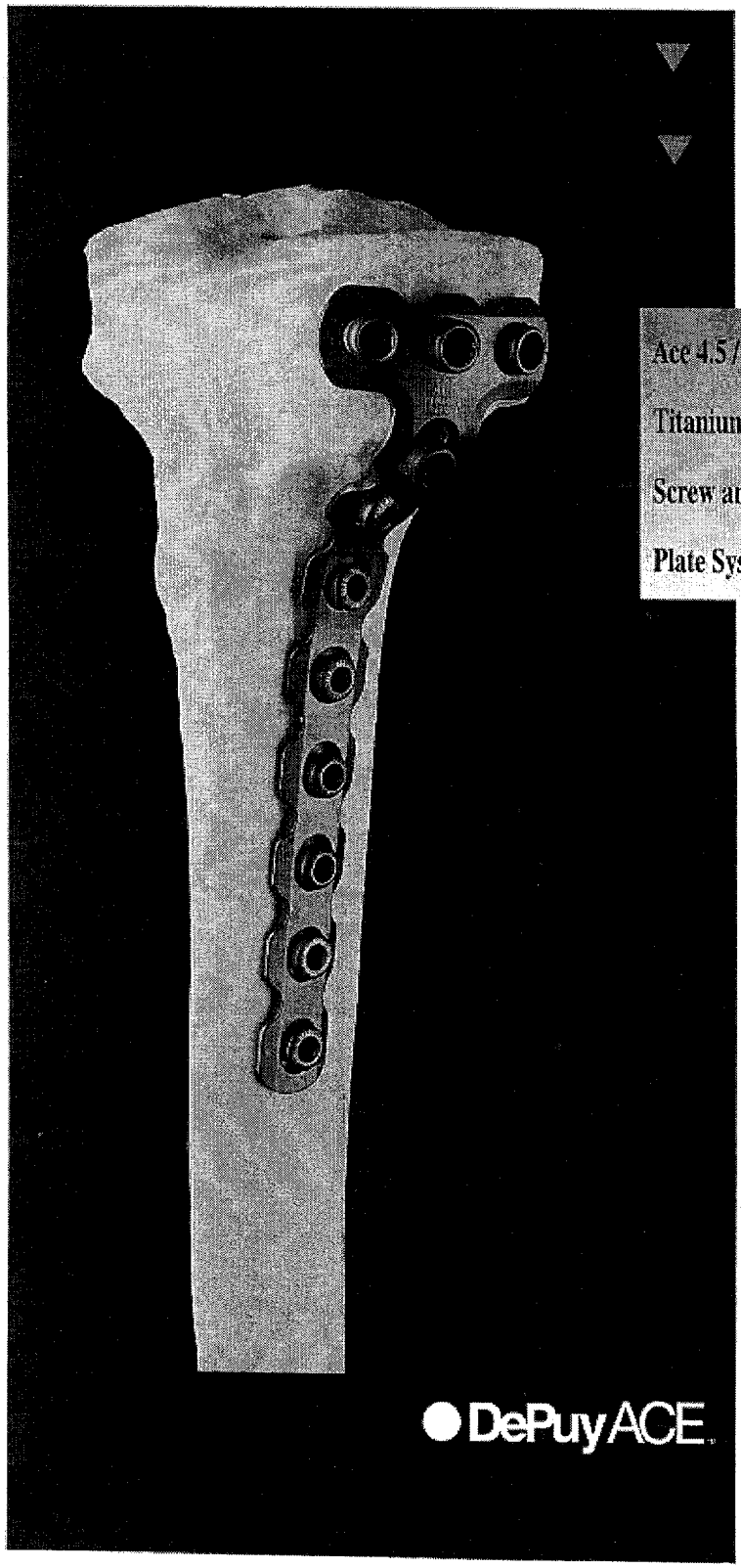
SURGICAL TECHNIQUE



Ace 4.5 / 5.0mm
Titanium Cannulated
Screw and Reconstruction
Plate System

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INTRODUCTION

When compared to 316L stainless steel, titanium alloy provides superior strength, malleability and fatigue resistance combined with a lower modulus of elasticity.[1] The properties of titanium alloy have been combined with a unique design to produce a state of the art fracture fixation system.

The System includes:

- 4.5mm Solid Self-Tapping Cortical Screws
- 4.5mm Self-Reaming, Self-Tapping Cannulated Cortical Screws
- 4.5mm Self-Reaming, Self-Tapping Cannulated Cortical Lag Screws
- 5.0mm Self-Reaming, Self-Tapping Cannulated Cancellous Lag Screws
- Straight Reconstruction Plates
- T-Plates in 4,6, and 8 hole lengths
- L-Plates in left and right configurations, 4,6, and 8 hole lengths

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Reconstruction Plates

The consequences of disuse osteoporosis,[2-6] such as fracture or refracture through the porotic segment, are well documented complications of the use of rigid stainless steel plates for internal fracture fixation.[7]

Titanium alloy provides stable fixation while reducing the structural weakening of bone during the remodeling phase of healing.[8] The lower modulus of elasticity of titanium alloy enhances stress transfer between the screw, plate and bone.[8]

Minimal periosteal coverage results in superior preservation of cortical vascularity.[9]

The greater strength and fatigue resistance of titanium alloy reduces the risk of plate breakage.[10]

In addition, the greater malleability and unique constant strength design of Ace reconstruction plates results in bending between the holes rather than at the holes during contouring.

4.5mm Solid Cortical Screws

The advanced design and titanium alloy of Ace screws combine to provide greater torque and yield strength than traditional stainless steel screws.[10]

Titanium Alloy Screws

The unique thread pattern of Ace solid, self-tapping cortical screws provide superior bone purchase and greater resistance to pullout.[11]

4.5mm Cannulated Fully Threaded Cortical Screws

4.5mm Cannulated Cortical Lag Screws

5.0mm Cannulated Cancellous Lag Screws

The use of titanium alloy in Ace cannulated screws provides greater torque and bending strength than traditional stainless steel screws.[11] The strength of titanium permits the use of a larger diameter guide wire (2mm) for more accurate screw placement and reduced risk of guide wire bending or breakage during insertion.

The strength of titanium alloy allows Ace cannulated screws to incorporate a self-reaming and self-tapping design that simplifies screw insertion and reduces operating time during both open and percutaneous procedures.

Ace cannulated screws are offered in the widest array of types and sizes presently available.

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Percutaneous Technique

Use of 4.5mm Cannulated Cortical Screws And

5.0mm Cannulated Cancellous Screws

Using a closed technique, reduction of the fracture is achieved and verified under image intensification.

The outer sheath (P/N 14235), with trochar sheath sleeve (P/N 14234) in place, is inserted through a 1cm incision and advanced to the bone **(FIGURE 1)**.

After removing the trochar sleeve, the 2mm sheath sleeve (P/N 14231.2.0) is inserted through the outer sheath and a 2.0mm guide wire (P/N 14179-9) is driven through the near cortex and across the fracture site to the required depth as confirmed under image intensification **(FIGURE 2)**.

Alternatively, if a K-wire was placed prior to insertion of the sheath and trochar the outer sheath with the 2mm sheath sleeve is inserted over the previously placed K-wire down to the bone.

Screw length is determined by removing the 2mm sheath sleeve and inserting the K-wire depth gauge (P/N 14232) over the K-wire, through the outer sheath, down to the cortical surface. The required screw length is read directly off the gauge at the end of the K-wire **(FIGURE 3)**.

Percutaneous Technique

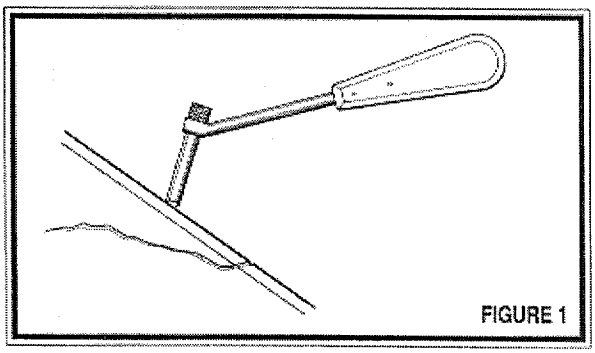

FIGURE 1

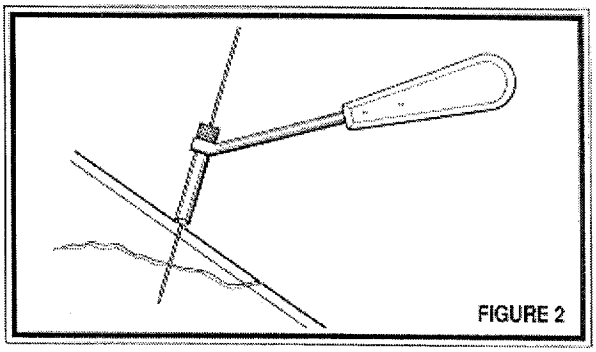

FIGURE 2

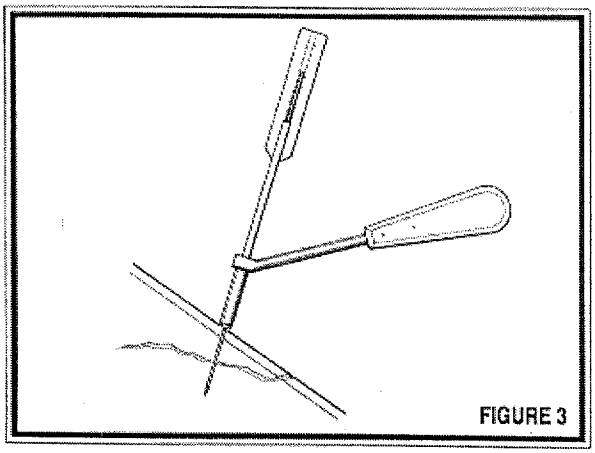

FIGURE 3

Insertion of the screw is performed by removing the K-wire depth gauge and placing the appropriate length screw over the K-wire and down through the outer sheath. The self-reaming, self-tapping screw is inserted either with power using the 4.5/5.0 screwdriver shank

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Percutaneous Technique

(P/N 14615) attached to the power adapter (P/N 14315), or manually using the 4.5/5.0 screwdriver shank attached to the T-handle (P/N 14316) **(FIGURES 4,5)**.

Final seating of the screw is always performed manually.

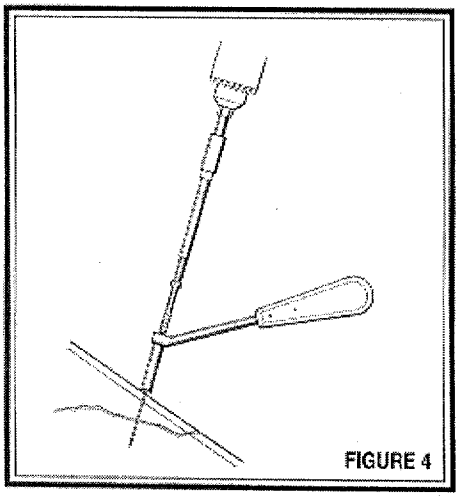

FIGURE 4

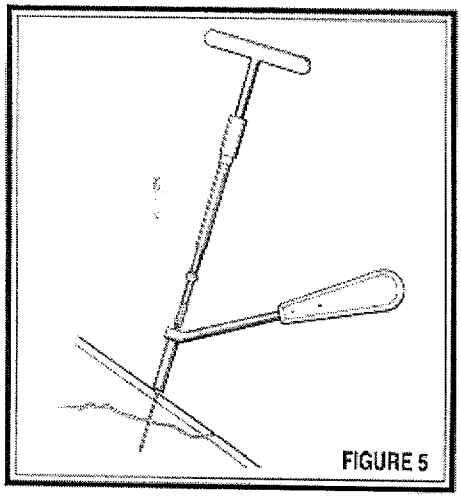

FIGURE 5

Percutaneous Technique

In hard, dense, or diaphyseal bone, the cortical wall is predrilled and tapped following screw length selection and prior to insertion of the screw.

Ace self-reaming, self tapping screws rarely require predrilling or tapping when used in metaphyseal bone. Should a screw fail to advance in metaphyseal bone, withdraw the screw and remove any foreign material from the cutting flutes at the tip of the screw and reattempt insertion. Should the screw still fail to advance, predrill and tap.

Predrilling and Tapping

Predrilling to the appropriate depth is performed using the 3.8mm cannulated drill (P/N 14622) placed over the K-Wire, through the outer sheath assembled with the 3.8mm sheath sleeve **(FIGURE 6)**.

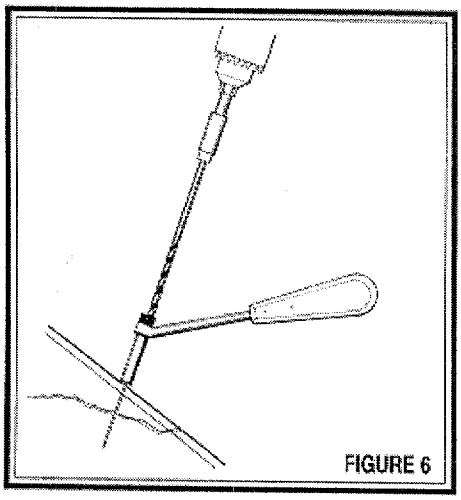

FIGURE 6

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Percutaneous Technique

Predrilling is followed by tapping either using the cannulated cancellous tap (P/N 14624) or cannulated cortical tap (P/N 14623) as appropriate, placed over the K-wire **(FIGURE 7)**.

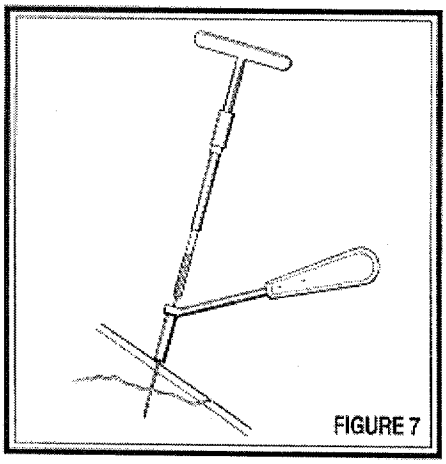

FIGURE 7

Following predrilling and tapping the screw is inserted as described above.

Note: During pre-drilling and/or tapping the K-wire may dislodge. Should this occur the K-wire may be removed and the screw inserted without the K-wire. Alternatively, the K-wire may be replaced under image intensification and the screw inserted over the new K-wire in the normal manner.

Open Technique

Use of 4.5mm Cannulated Cortical Screws

And 5.0mm Cannulated Cancellous Screws

During Open Reduction

Following a standard surgical approach to expose the bone, the fracture is reduced and held using a 2.0mm K-wire or wires. Care must be taken to determine that the depth of the K-wire for guided screw placement is appropriate for the length of screw required for fixation.

Following reduction and appropriate placement of the K-wires, the K-wire depth gauge is placed over the K-wire down to the cortical surface. The required screw length is read directly off the gauge at the end of the K-wire **(FIGURE 8)**.

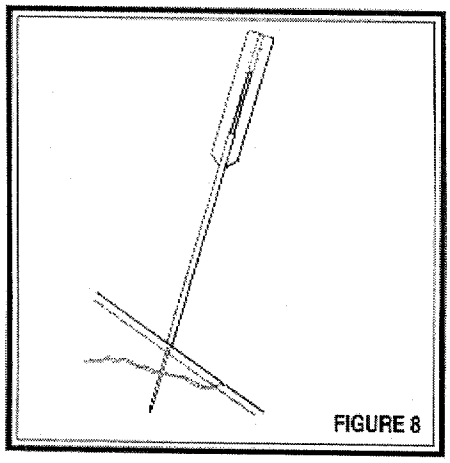

FIGURE 8

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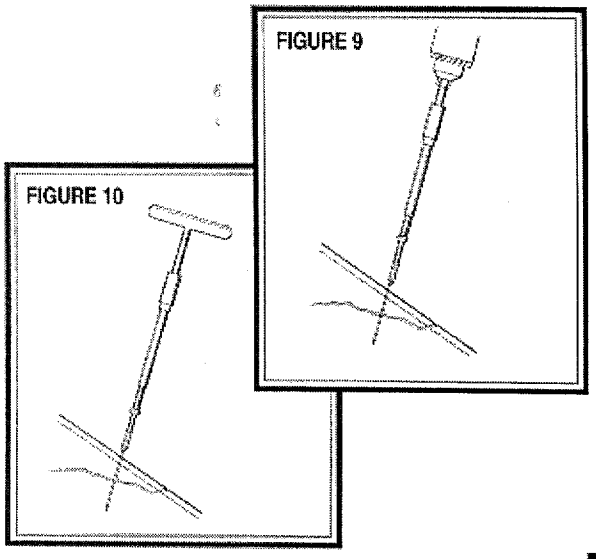
Open Technique

The appropriate self-reaming, self-tapping screw is inserted either with power using the 4.5/5.0 screwdriver shank attached to the power adapter, or manually using the 4.5/5.0 screwdriver shank attached to the T-handle **(FIGURES 9,10)**.

Final seating of the screw is always performed manually.

In hard, dense, or diaphyseal bone, the cortical wall is predrilled and tapped following screw length selection and prior to insertion of the screw.

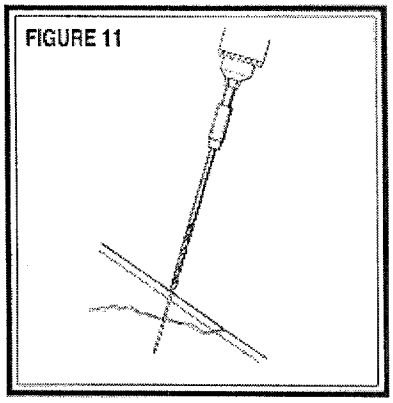
Ace self-reaming, self-tapping screws rarely require predrilling or tapping when used in metaphyseal bone. Should a screw fail to advance in metaphyseal bone, withdraw the screw and remove any foreign material from the cutting flutes at the tip of the screw and reattempt insertion. Should the screw still fail to advance, predrill and tap.



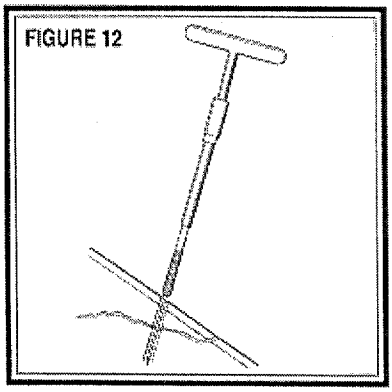
Open Technique

Predrilling and Tapping

Predrilling to the appropriate depth is performed using the 3.8mm cannulated drill placed over the K-wire **(FIGURE 11)**.



Predrilling is followed by tapping using either the cannulated cancellous tap or cannulated cortical tap as appropriate, placed over the K-wire **(FIGURE 12)**.



Following predrilling and tapping the screw is inserted as described above.

Note: During predrilling and/or tapping the K-wire may dislodge. Should this occur the K-wire may be removed and the screw inserted without the K-wire. Alternatively, the K-wire may be replaced under image intensification and the screw inserted over the new K-wire in the normal manner.

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Open Lag Technique

Use of 4.5mm Solid Cortical Screws During Open Reduction

The fracture is reduced and secured with bone holding forceps, and both cortices are penetrated with the 3.8mm twist drill (P/N 14621) **(FIGURE 13).**

The outer sheath (P/N 14235) when used with the appropriate drill or K-wire sheath sleeve may be used as a freehand drill or K-wire guide during open procedures.

FIGURE 13

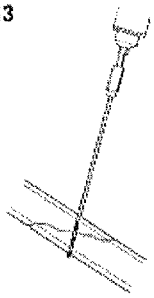


FIGURE 14

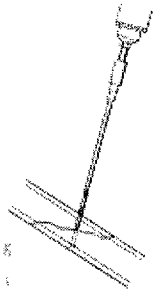
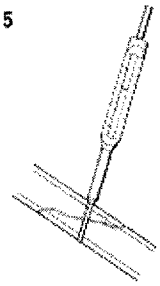


FIGURE 15



Open Lag Technique

The "gliding" hole is made by over drilling the near cortex up to the fracture line with the 4.8mm twist drill (P/N 14625) **(FIGURE 14).**

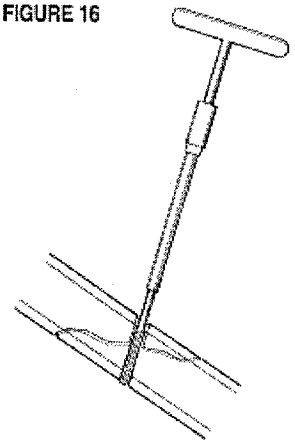
Required screw length is determined using the hook depth gauge (P/N 14045) **(FIGURE 15).**

The self-tapping solid cortical screw is inserted either with power using the 4.5/5.0 screwdriver shank attached to the power adapter , or manually using the 4.5/5.0 screwdriver shank attached to the T-handle **(SEE FIGURES 9,10).**

Final seating of the screw is always performed manually.

Note: In very hard, dense, or diaphyseal bone, tapping the far cortex with the cannulated cortical tap (P/N 14623) may be necessary **(FIGURE 16).**

FIGURE 16



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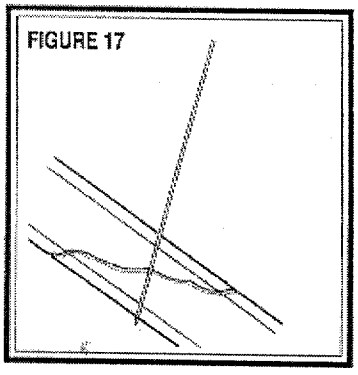
Open Lag Technique

4.5mm Cannulated Cortical Lag Screws

The Ace 4.5mm cannulated cortical lag screw (P/N 14250-Length) has been specifically designed for situations requiring lagging with a cannulated cortical screw. However, guided screw lagging with the Ace fully threaded cannulated cortical screw (P/N 14200-Length) may be performed as follows.

Use of 4.5mm Cannulated Cortical Screws To Lag Bone Fragments

A 2.0mm K-wire is inserted through the near cortex, across the fracture site and through the far cortex in the position selected for placement of the screw. Care must be taken to determine that the depth of the K-wire for guided screw placement is appropriate for the length of screw required for fixation **(FIGURE 17)**.

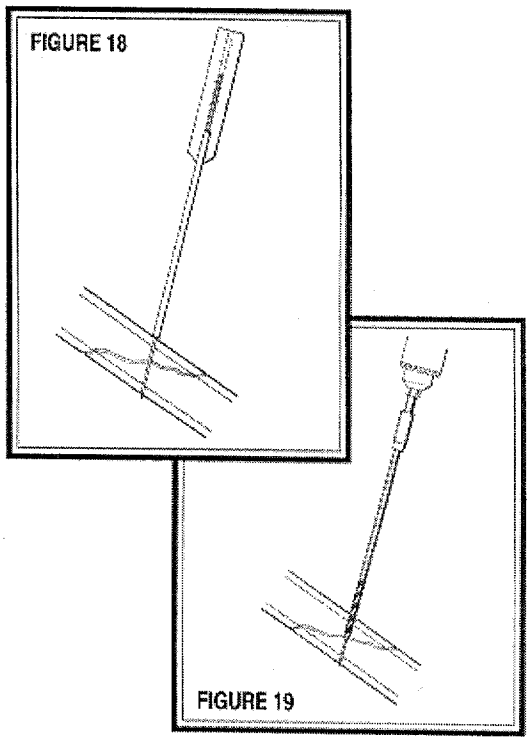


Following correct placement of the K-wire, the K-wire depth gauge is placed over the K-wire and advanced to the bone. Screw length is read directly off the gauge at the end of the K-wire **(FIGURE 18)**.

After removing the K-wire depth gauge, the 4.8mm cannulated drill is placed over the K-wire and the near cortex is overreamed to

Open Lag Technique

a 4.8mm diameter up to the fracture line to produce the "gliding hole" **(FIGURE 19)**.



Following reaming of the near cortex the appropriate length screw is placed over the K-wire. The self-reaming self-tapping screw may be inserted either with power using the 4.5/5.0 screwdriver shank attached to the power adapter, or manually using the 4.5/5.0 screwdriver shank attached to the T-handle **(SEE FIGURES 9,10)**.

Final seating of the screw is always performed manually.

In very hard, dense, or diaphyseal bone, the far cortex should be predrilled and tapped prior to screw insertion to prevent migration of the fragment to be lagged.

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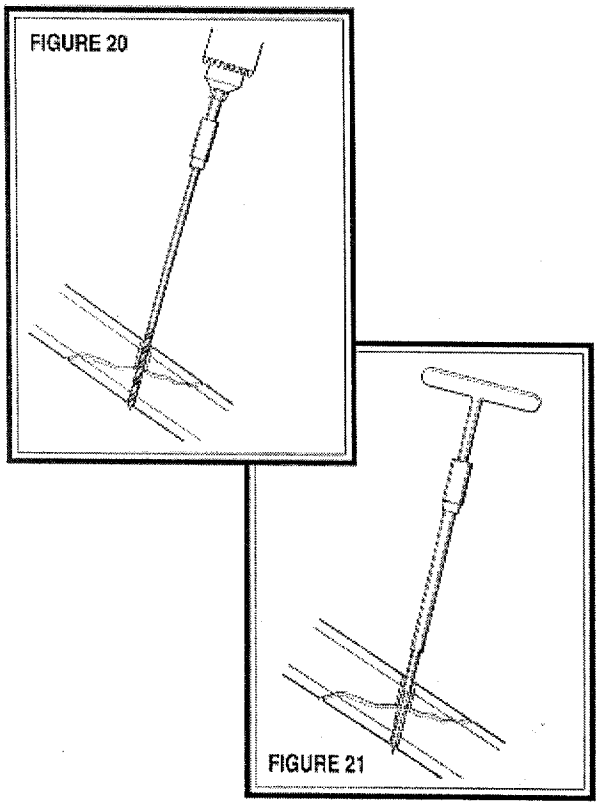
Open Lag Technique

Predrilling of the far cortex is performed using the 3.8mm cannulated drill placed over the K-wire **(FIGURE 20)**.



Predrilling is followed by tapping using the cannulated cortical tap placed over the K-wire **(FIGURE 21)**.

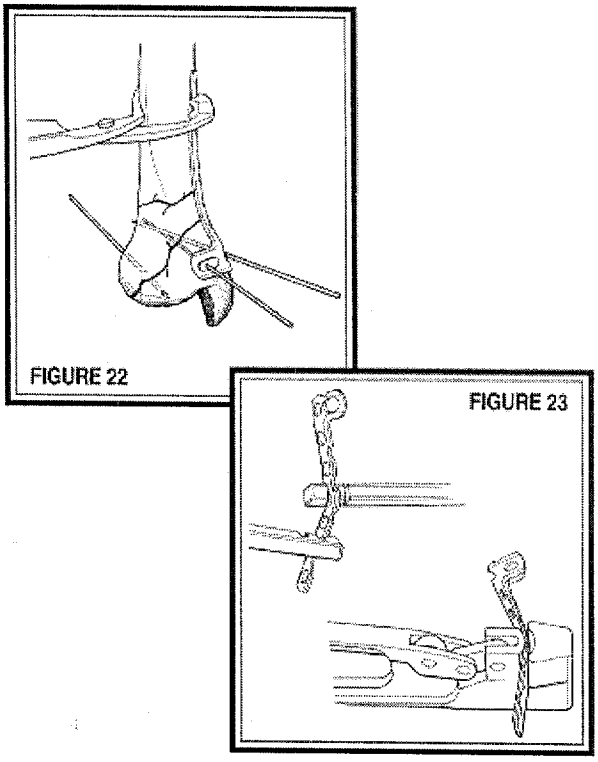
Following predrilling and tapping the screw is inserted as described previously.

Note: During predrilling and/or tapping the K-wire may dislodge. Should this occur the K-wire may be removed and the screw inserted without the K-wire. Alternatively, the K-wire may be replaced under image intensification and the screw inserted over the K-wire in the normal manner.

Plating Technique

Plates With Cannulated and Solid Screws

The bone is exposed using the surgical approach appropriate to the fracture. The fracture is reduced and the position of fragments maintained using 2.0mm K-wires. These wires may be placed in the appropriate position for screw fixation when necessary **(FIGURE 22)**.



Associated diaphyseal fractures are reduced and a properly contoured 4.5mm titanium alloy reconstruction plate is held in place with bone holding forceps.

To facilitate contouring of Ace reconstruction plates, disposable aluminum templates (P/N 14305) are available to assist in determining the contours required for the specific fracture. Bending pliers

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(P/N 14324) and bending irons (P/N 14320) are used to form the appropriate titanium alloy reconstruction plates **(FIGURE 23)**.

Care should be taken not to overbend or rebend the plates beyond 15' between holes as this may damage the integrity of the plate. The Ace bending pliers are designed to produce maximum allowable bend, (refer to caution statement).

Because of their superior strength all Ace 4.5mm, 5.0mm and 6.5mm cannulated and solid screws may be used in any combination in conjunction with Ace titanium alloy reconstruction plates. Screws should be selected according to the location and type of bone involved.

Using A K-Wire To Guide A Cannulated Screw Through A Plate

Using the drill and K-wire guide (P/N 14350) with the 2.0mm guide sleeve, (P/N 14351-2.0) a 2.0mm K-wire is centered in the appropriate hole of the previously contoured and positioned plate **(FIGURE 24)**.

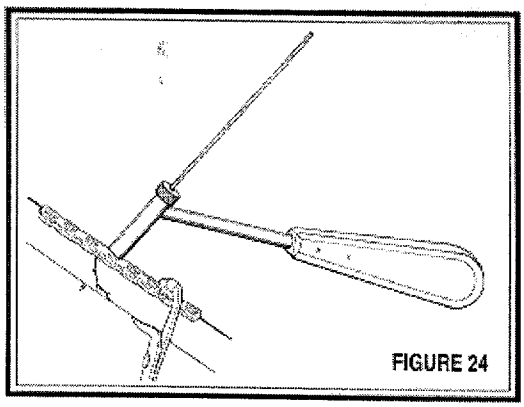

FIGURE 24

Plating Technique

With the K-wire positioned, the appropriate screw length is determined using the K-wire depth gauge, placed over the K-wire against the surface of the plate. Screw length is read directly off the gauge at the end of the K-wire **(FIGURE 25)**.

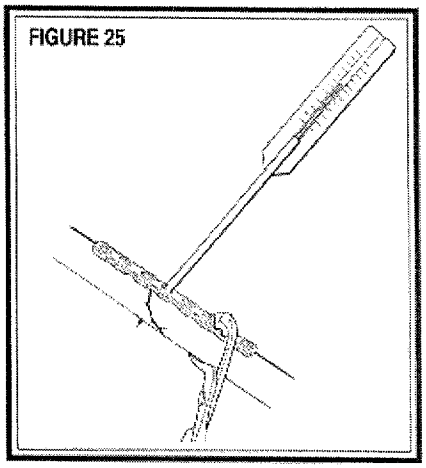

FIGURE 25

The K-wire depth gauge is removed and the appropriate length screw is placed over the K-wire. The self-reaming, self-tapping screw is inserted either with power using the 4.5/5.0 screwdriver shank attached to the power adapter, or manually using the 4.5/5.0 screwdriver shank attached to the T-handle **(SEE FIGURES 9,10)**.

In diaphyseal bone predrilling and tapping may be required **(SEE FIGURES 6,7)**.

Final seating of the screw should always be performed manually.

Note: The drill and K-wire guide positions the K-wire or drill in the "neutral" position.

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Plating Technique

Inserting Solid Or Cannulated Screws Through A Plate Without A K-Wire

Both solid and cannulated screws in the Ace 4.5/5.0mm titanium alloy reconstruction plate system may be used to anchor a plate without a guiding K-wire.

Using the drill and K-wire guide assembled with the 3.8mm drill guide sleeve, (P/N 14351-3.8), the 3.8mm twist drill is centered in the appropriate hole in the plate and a hole is prepared **(FIGURE 26)**.

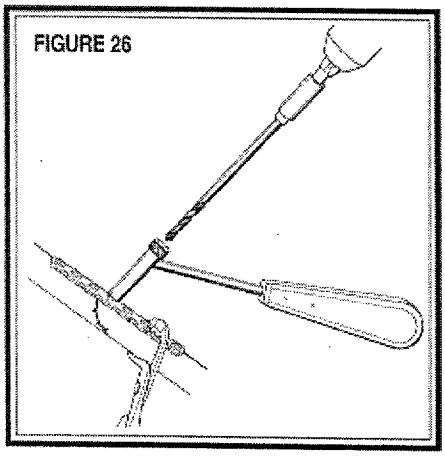

FIGURE 26

Following drilling, required screw length is determined using the hook depth gauge (P/N 14045) placed with the body of the gauge against the surface of the plate **(FIGURE 27)**.

The appropriate length self-tapping solid or cannulated screw is inserted either with power using the 4.5/5.0 screwdriver shank attached to the power adapter or manually, using the 4.5/5.0 screwdriver shank attached to the T-handle **(SEE FIGURES 9,10)**.

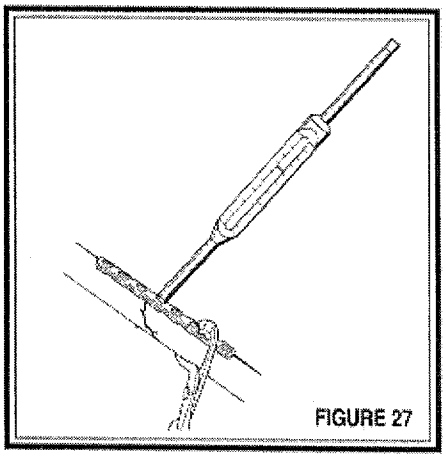

FIGURE 27

Final seating of the screw is always performed manually.

To use the 4.5mm solid cortical bone screw or the 4.5mm cannulated cortical bone screw to lag a bone fragment in conjunction with a plate, the open lag techniques described previously are applied. The appropriate drill bits and K-wires must be centered in the plate holes using the drill and K-wire guide (P/N 14350) assembled with either the 3.8mm drill guide sleeve (P/N 14351-3.8), the 4.8mm drill guide sleeve (P/N 14351-4.8), or the 2.0mm K-wire guide sleeve (P/N 14351-2.0), as required **(FIGURE 28)**.

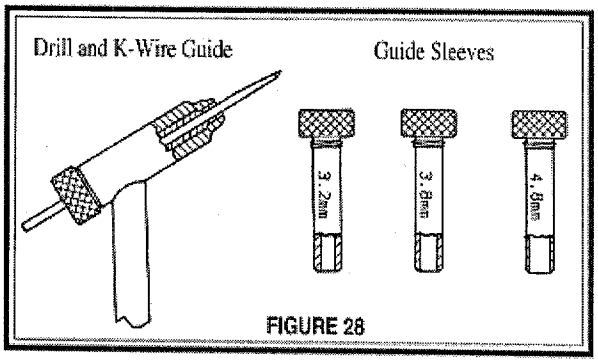

FIGURE 28

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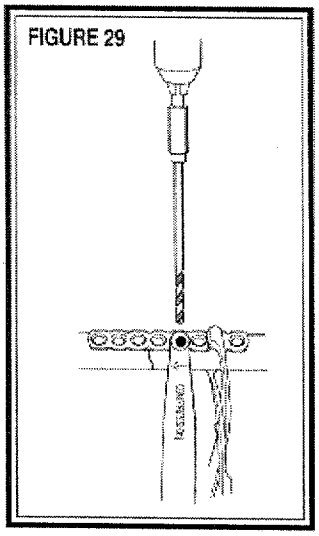
Plating Technique

Interfragmentary Compression With Ace Titanium Alloy Reconstruction Plates

The oval holes of Ace reconstruction plates permit compression of fracture fragments. Compression of approximately 1mm is achieved during final seating of the screw in the plate if the screw is placed in an eccentrically drilled hole.

The eccentric hole is produced using the 3.8mm twist drill (P/N 14621) positioned with the special compression drill guide (P/N 14356) engaged completely in the oval screw hole **(FIGURE 29)**.

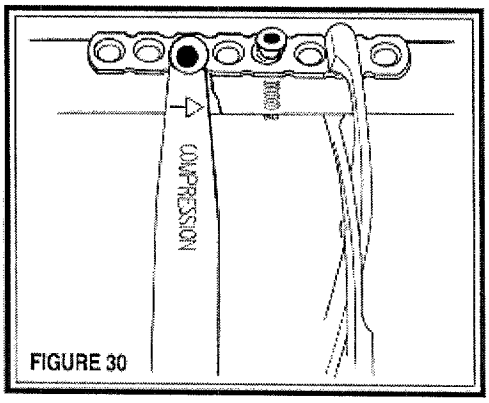


The handle of the drill guide must point towards the surgeon.

With the compression drill guide handle towards the surgeon and the arrow pointing towards the fracture line, the drill will be positioned appropriately to produce the eccentric "compression screw" hole **(FIGURE 30)**.

Plating Technique

Note: Only Ace solid cortical bone screws are recommended for use in compression plating techniques.



Use Of Ace 6.5mm Cannulated Cancellous Screws With 4.5/5.0mm Reconstruction Plates

Ace 6.5mm cannulated cancellous lag screws are available in 22mm (P/N 14196- Length) and 40mm (P/N 14197-Length) thread lengths.

In order to use Ace 6.5mm screws with Ace titanium alloy reconstruction plates, Ace 6.5mm screw instrumentation is required.

Use of Ace 6.5mm Cannulated Cancellous Lag Screws with A K-Wire To Anchor A Plate

The drill and K-wire guide (P/N 14350) is assembled with the 3.2mm K-wire guide sleeve, (P/N 14351-3.2) and used to center a 3.2mm K-wire in the appropriate screw hole of the previously contoured and positioned plate. Care must be taken to insert the K-wire to the appropriate depth **(FIGURE 31)** NEXT PAGE.

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Plating Technique

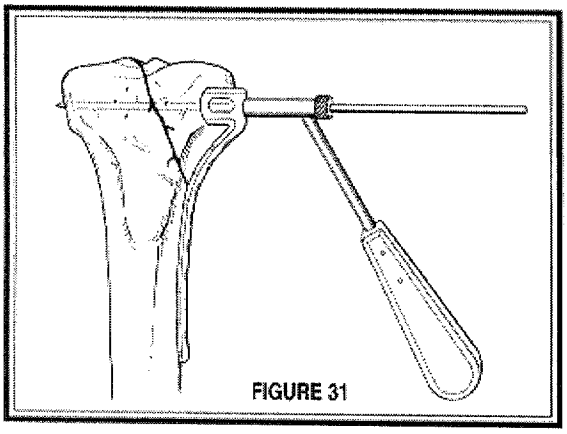

FIGURE 31

With the K-wire in position the guide is removed and required screw length is determined using the 6.5mm K-wire depth gauge (P/N 14115) placed over the K-wire and positioned against the surface of the plate. The appropriate screw length is read directly off the gauge at the end of the K-wire **(FIGURE 32)**.

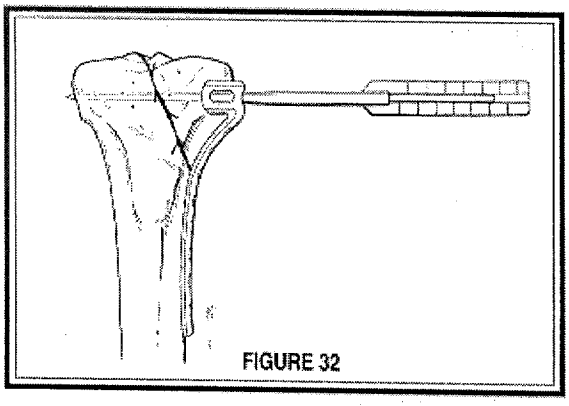

FIGURE 32

The K-wire depth gauge is removed and the appropriate length screw is placed over the K-wire. The self-reaming, self-tapping screw may be inserted either with power using the 6.5mm screwdriver shank (P/N 14201) coupled with the power adapter (P/N 14315), or manually

Plating Technique

with the 6.5mm screwdriver shank attached to the T-handle (P/N 14316) **(FIGURE 33, 34)**.

Final seating of the screw should always be performed manually.

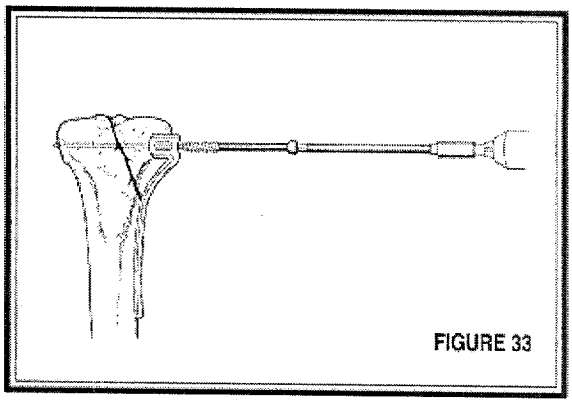

FIGURE 33

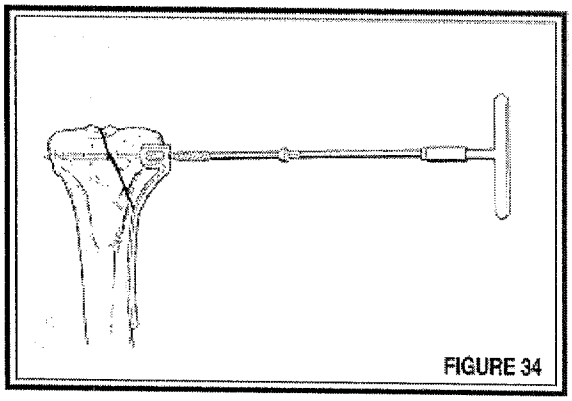

FIGURE 34

Ace self-reaming, self tapping screws rarely require predrilling or tapping when used in metaphyseal bone. Should a screw fail to advance in metaphyseal bone, withdraw the screw and remove any foreign material from the cutting flutes at the tip of the screw and reattempt insertion. Should the screw still fail to advance predrill and tap.

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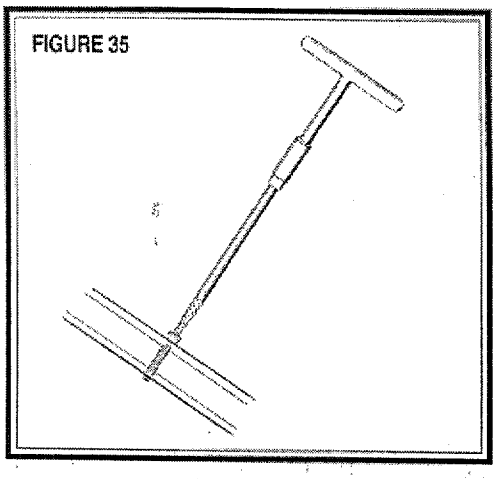
Screw Removal

Screws may be removed either with power using the 4.5/5.0 screwdriver shank (P/N 14615) attached to the power adapter (P/N 14315), or manually using the 4.5/5.0 screwdriver shank attached to the T-handle (P/N 14316) **(SEE FIGURES 4,5).**

Screw removal should always be started manually.

Should cannulated screw removal become difficult, the easy out extractor (P/N 14620) should be used for screw extraction. The easy out extractor must be used manually in conjunction with the T-handle. The tip of the extractor is inserted into the screw cannula and the extractor is turned counter clockwise while applying firm forward pressure. The easy out extractor cuts into the screw shaft to facilitate removal. The easy out extractor may be used even if the head or shaft of the screw is not intact **(FIGURE 35).**



Note: Under no circumstances should pliers or similar devices be used to grip the screw head as this will damage the screw and could lead to head breakage.

Ancillary Components

Countersinking of screws may be performed using the cannulated countersink (P/N 14618) attached to the T-handle (P/N 14316).

Traditional plain washers (P/N 14260) as well as cup washers (P/N 14261) are available for 4.5/5.0mm screws when used in osteoporotic bone.

A pear handle driver (P/N 14317) is available for use with all 4.5/5.0mm and 6.5mm instruments.

Equipment Maintenance

Bending pliers, P/N 14324 must be lubricated with surgical instrument lubricant following each cleaning, prior to autoclaving.

Special care should be exercised during the cleaning of cannulated instrumentation to assure that all foreign material is removed from the inside of the instrument.

The high strength of Ace titanium alloy implants relative to similar stainless steel implants may result in unexpected wear of some instrumentation. Ace instruments are designed for maximum strength and longevity within the limits of the materials presently available. Regular inspection and careful maintenance will increase the useful life of all instrumentation.

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Cautions

Use only Ace bending instruments when contouring Ace titanium alloy plates.

Do not straighten or rebend plates after initial contouring.

When using bending irons do not exceed the maximum bend of 15° between any two holes. Bending pliers are adjusted to produce maximum allowable bend.

Bending pliers, P/N 14324 must be lubricated with surgical instrument lubricant following each cleaning, prior to autoclaving.

Use of damaged or misused instrumentation during plate bending may cause surface abrasion resulting in possible plate damage.

Use of K-wires that are damaged or bent may result in unwanted movement of the K-wire during screw insertion, predrilling, and/or tapping.

During cannulated screw insertion the surgeon should periodically check for undesired advancement of the guide wire.

The text and schematic drawings included in this protocol are general instructions for the use of Ace instrumentation only. Placement of screws and plates for the stabilization of specific fractures must be determined using the best judgment of the surgeon.

Indications

The Ace 4.5/5.0mm screw and reconstruction plate system is designed for fixation of the following fractures:

- Metaphyseal fractures of the distal tibia, femur, humerus and radius
- Metaphyseal fractures of the proximal tibia, humerus and radius
- Fractures of the medial and lateral malleolus
- Fractures of the tibial plateau
- Fractures of the olecranon process and os calcis
- Fractures of the pelvis

Contraindications

- Ace 4.5/5.0mm screw and reconstruction plate system is contraindicated in the presence of on going sepsis and situations in which malignant primary or metastatic tumors or severe osteoporosis preclude adequate bone support for the device.

- Ace 4.5/5.0 straight reconstruction plates are contraindicated for diaphyseal fractures of the femur and tibia.

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(8) Uhthoff, H.K., Bardos, D.I., Liskova-Kiar, M.: The Advantages Of Titanium Alloy Over Stainless Steel Plates For The Internal Fixation Of Fractures. British Editorial Society Of Bone and Joint Surgery, 63-B, No.3, 427-433, 1981

(9) Perren, S.M., Cordey, J. Rahn, B.A., Gautier ,E., Schneider, E.: Early Temporary Porosis Of Bone Induced By Internal Fixation Implants. Clin. Orthop. 232: 139-151, 1988.

(10) Department of Orthopaedic Research, Hospital of the Good Samaritan, Los Angeles, CA

(11) Orthopaedic Biomechanics Laboratory, Metropolitan and Hennepin County Medical Centers, Minneapolis, MN.

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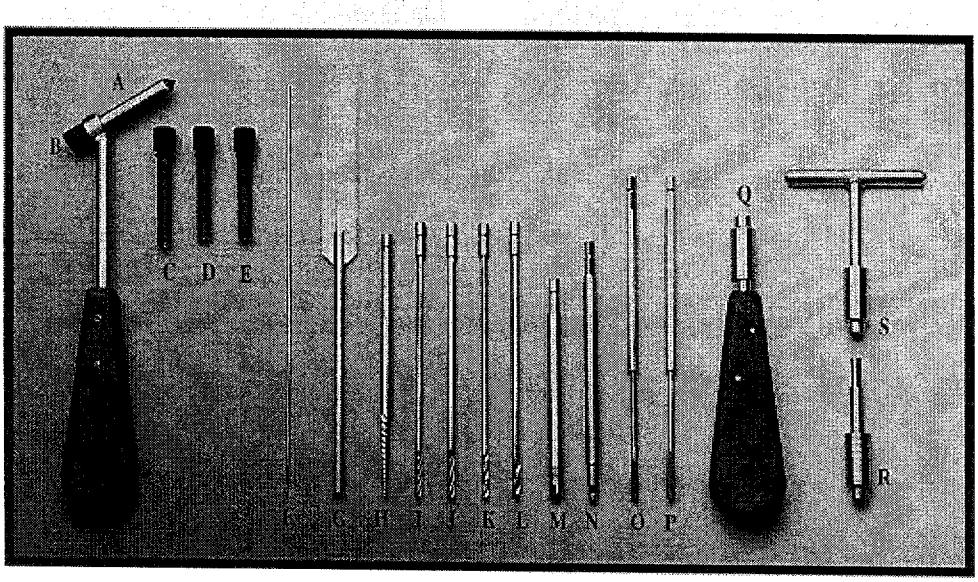
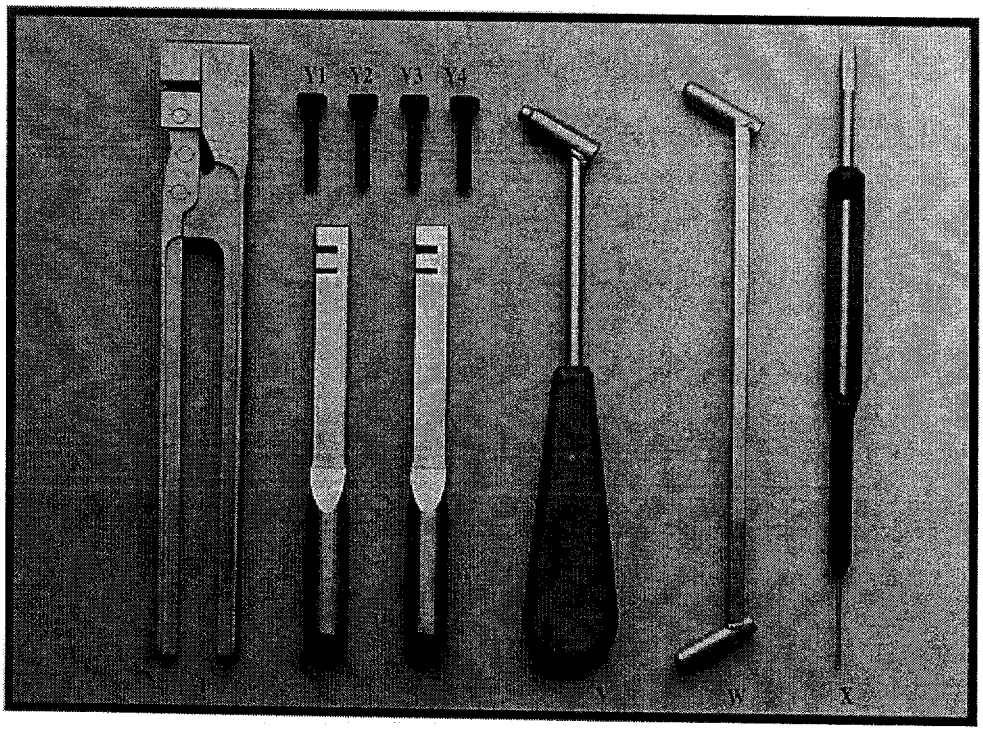
Instrumentation



A. Outer Sheath
B. Trochar Sheath Sleeve
C. 3.8mm Sheath Sleeve
D. 4.8mm Sheath Sleeve
E. 2.0mm Sheath Sleeve
F. 2.0mm K-Wire
G. K-Wire Depth Gauge
H. Easy Out
I. 3.8mm Cannulated Drill
J. 4.8mm Cannulated Drill
K. 3.8mm Twist Drill
L. 4.8mm Twist Drill
M. Countersink
N. Screwdriver Shank
O. 4.5mm Cortical Tap
P. 5.0mm Canncellous Tap
Q. Pear Handle*
R. Power Adapter
S. T-Handle



T. Bending Pliers
U. Bending Irons
V. Drill & K-Wire Guide
W. 4.5mm Compressing
X. Hook Depth Gauge
Y1. 2.0mm Guide Sleeve
Y2. 3.2mm Guide Sleeve
Y3. 3.8mm Guide Sleeve

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Standard 4.5/5.0mm Screw & Plate System Parts List

Straight Plates

14340-3	3 Hole
14340-4	4 Hole
14340-6	6 Hole
14340-8	8 Hole
14340-10	10 Hole
14340-12	12 Hole
14340-14*	14 Hole
14340-16*	16 Hole

"T" Plates

14342-4	4 Hole
14342-6	6 Hole
14342-8	8 Hole

"L" Plates, Left

14344-4	4 Hole
14344-6	6 Hole
14344-8	8 Hole

"L" Plates, Right

14345-4	4 Hole
14345-6	6 Hole
14345-8	8 Hole

4.5mm Solid Cortical Bone Screws[1]

14022-xx	20 to 60mm in 2mm increments 65 to 80mm in 5mm increments

4.5mm Cannulated Cortical Bone Screws[1]

14200-xx	20 to 50mm in 2mm increments 55 to 70mm in 5mm increments

4.5mm Cannulated Cortical Lag Screws[1]

14250-xx	30 to 50mm in 2mm increments 55 to 70mm in 5mm increments

5.0mm Cannulated Cancellous Lag Screws[1]

14225-xx	30 to 50mm in 2mm increments 55 to 70mm in 5mm increments

*Special Order

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

4.5/5.0mm Instrumentation

14045	Hook Depth Gauge
14231-2.0	2.0mm Sheath Sleeve
14232	K-Wire Depth Gauge
14234	Trochar Sheath Sleeve
14235	Outer Sheath
14239-3.8	3.8mm Sheath Sleeve
14239-4.8	4.8mm Sheath Sleeve
14315	Power Adaptor
14316	T-Handle
14317	Pear Handle
14320	Bending Iron
14324	Bending Pliers
14350	Drill and K-Wire Guide
14351-2.0	2.0mm Guide Sleeve
14351-3.2	3.2mm Guide Sleeve
14351-3.8	3.8mm Guide Sleeve
14351-4.8	4.8mm Guide Sleeve
14356	4.5mm Compression Drill Guide
14615	Screwdriver Shank
14618	Countersink

4.5/5.0mm Disposables

10405-9	2.0mm Steinman Pin
14179-9	2.0mm K-Wire Bayonet Tip
14305-4	Template, 4 Hole
14305-8	Template, 8 Hole
14620	Easy Out
14621	3.8mm Solid Twist Drill
14622	3.8mm Cannulated Drill
14623	4.5mm Cortical Tap
14624	5.0mm Cancellous Tap
14625	4.8mm Solid Twist Drill
14626	4.8mm Cannulated Drill

Miscellaneous

14260	4.5/5.0 Flat Washer
14261	4.5/5.0 Countersink Washer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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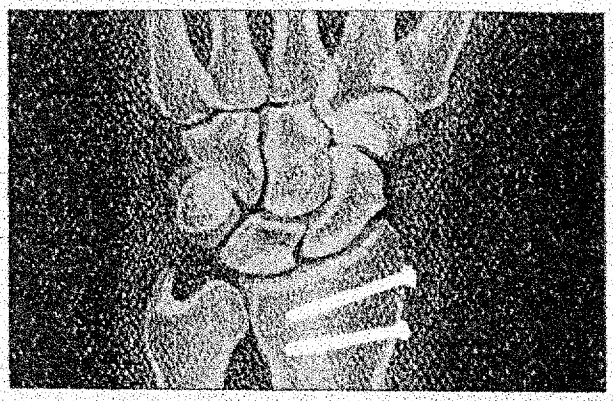
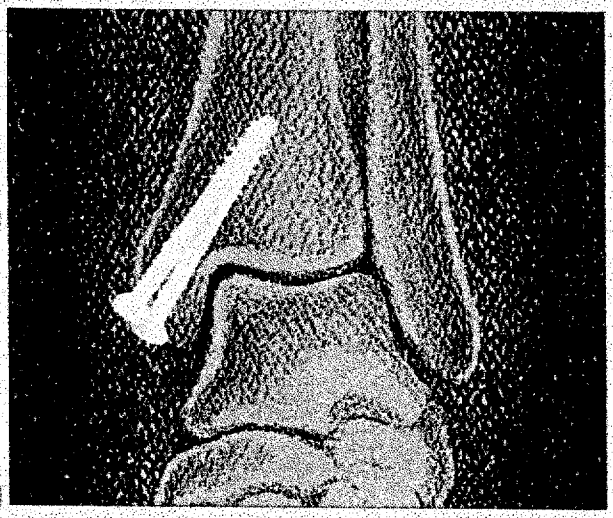
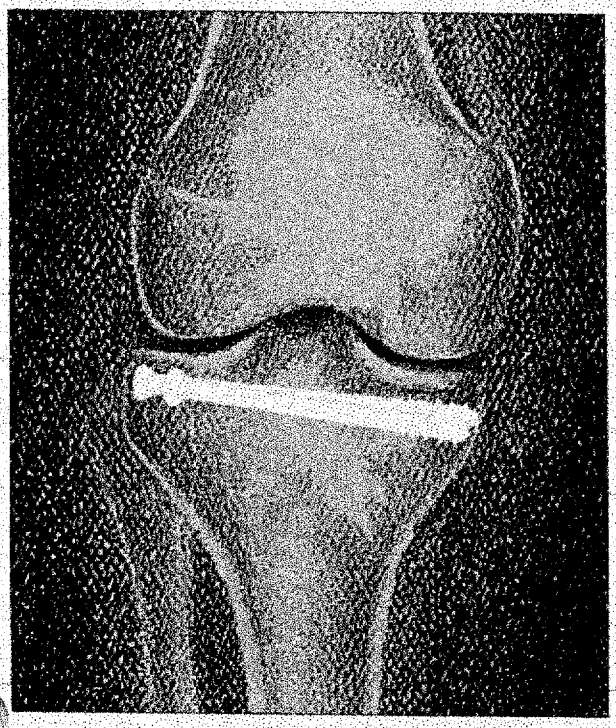


The SYNTHES Cannulated Screw System



A Complete System of Cannulated Screws

- 3.5 mm
- 4.5 mm
- 7.0 mm



SYNTHES

Original Instruments and Implants of the Association for the Study of Internal Fixation—AO/ASIF

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The System

The SYNTHES Cannulated Screw System consists of three sets: the 3.5 mm Cannulated Screw Set, the 4.5 mm Cannulated Screw Set, and the 7.0 mm Cannulated Screw Set. Together, these three sets provide a cannulated screw option for most clinical situations.

Implants

Clinically Based Designs
- Appropriate screw dimensions for each clinical application

Reverse-Cutting Flutes
- Facilitate screw removal, especially in dense bone

Wide Range of Sizes
- For all applications
- Expands treatment options

316L Stainless Steel
- Cold-worked for strength
- AO/ASIF implant quality; compatible with SYNTHES stainless steel systems

Instruments

Simple, Precise Instrumentation
- Carries SYNTHES reputation for quality
- Easy to use

Threaded Guide Wires
- Spade-point cutting tips facilitate accurate insertion
- Threaded tips reduce the possibility of pullout

Graphic Cases
- Organize instruments in order of use to facilitate procedure
- Simplify component identification and inventory

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications

Fractures of the carpals and metacarpals

Radial styloid fractures

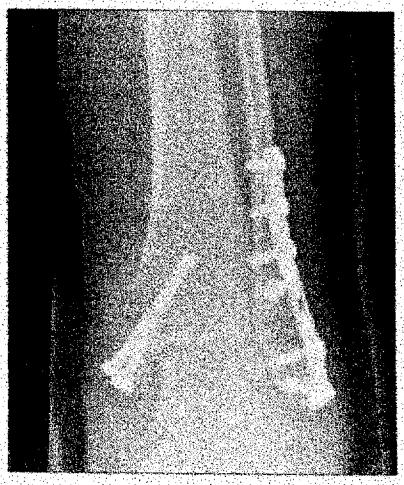
3.5 mm Cannulated Screws

Small fragments in fractures, such as:

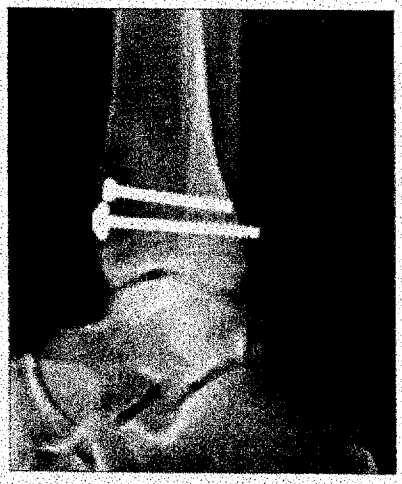
- Fractures of the carpals and metacarpals
- Fractures of the metatarsals
- Radial styloid fractures

Also:

- Fixation of metacarpal and metatarsal osteotomies
- Arthrodeses of the carpals and phalanges
- Osteochondritis dissecans
- Ligament fixation



Malleolar fractures



Pilon fractures

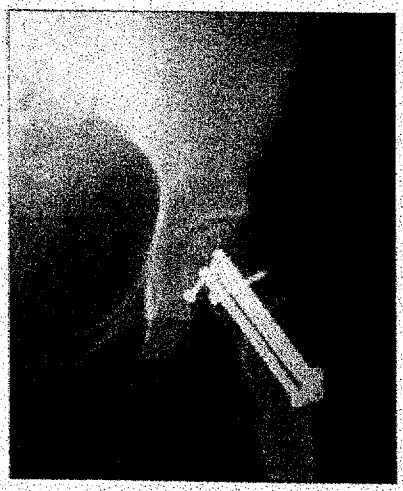
4.5 mm Cannulated Screws

Intermediate-sized fragments in fractures, such as:

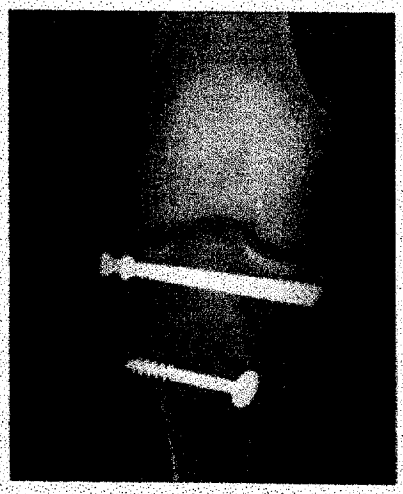
- Malleolar and pilon fractures
- Acetabular and pelvic fractures
- Fractures of the calcaneus and talus
- Fractures of the proximal and distal humerus
- Patellar fractures
- Certain tibial plateau fractures

Also:

- Arthrodeses of the tarsals
- Ligament fixation of the proximal humerus



Intracapsular fractures of the hip



Tibial plateau fractures

7.0 mm Cannulated Screws

Large fragments in fractures, such as:

- Intracapsular fractures of the hip
- Tibial plateau fractures
- Pediatric femoral neck fractures
- Femoral intercondylar fractures

Also:

- Sacroiliac joint disruptions
- Ankle arthrodeses
- Slipped capital femoral epiphyses

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.5 mm Cannulated Screw Set [105.03]

Designed for fixation of small bones and small bone fragments

Implant

3.5 mm Thread Diameter/ 1.25 mm Pitch
- For excellent purchase and stable interfragmentary compression

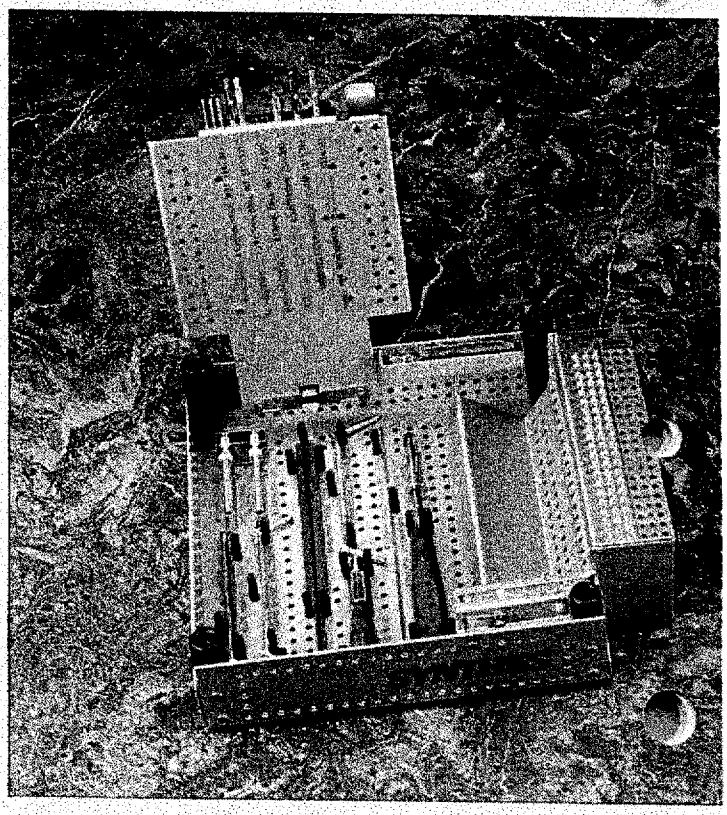
2.5 mm Screw Head Height/ 5.0 mm Screw Head Diameter
- For low profile in or near joint surfaces
- Can be used through the following implants:
  - 2.7 mm L-Plates and T-Plates
  - Small T-Plates
  - Cervical Vertebrae Plates
  - Cloverleaf Plates
  - Quarter-Tubular Plates
  - Multiple Fragment Plate
  - Spiked Washer

1.35 mm Cannulation
- Accommodates a 1.25 mm guide wire for precise screw placement without compromising implant strength

Tapered Tip
- Minimizes fragment displacement during insertion

Reverse-Cutting Flutes
- Facilitate screw removal

Wide Range of Screws
- For many clinical situations
- Partially or fully threaded
- Available in 10 mm–50 mm lengths

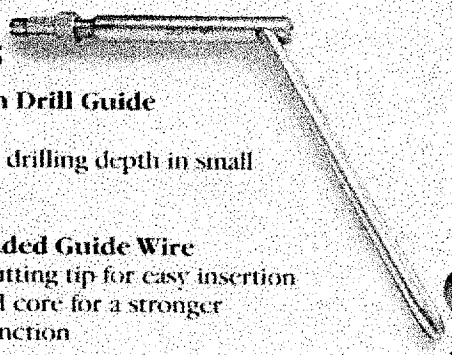


The 3.5 mm and 4.5 mm Cannulated Screw cases are a reduced size. They can be used individually or together (in the same space as a single full-sized set), offering multipurpose use of the systems:

- Individually, for separate surgical cases, or
- In combination, for the multiple-trauma patient.

Together, the systems offer a complete set of special implants for use in small and intermediate-sized fragments.

Instruments



3.5 mm/2.7 mm Drill Guide with Stop
- For controlled drilling depth in small fragments

1.25 mm Threaded Guide Wire
- Spade-point cutting tip for easy insertion
- Tapered thread core for a stronger shaft/thread junction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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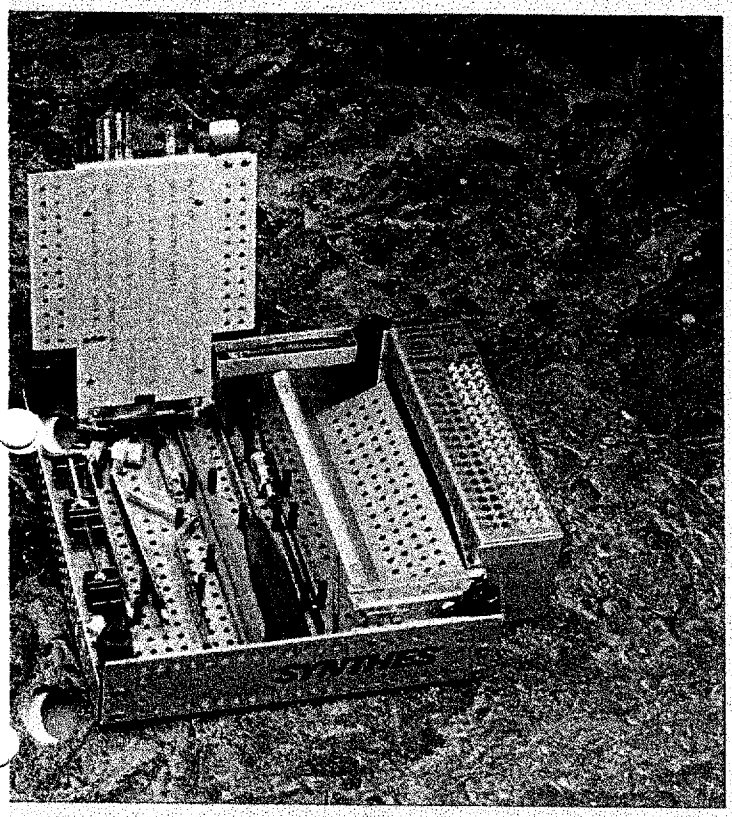
4.5 mm Cannulated Screw Set [105.04]

Designed for fixation of intermediate-sized fragments of metaphyseal bone



Implant

4.5 mm Thread Diameter/ 2.7 mm Core Diameter/ 1.75 mm Pitch/Cancellous Thread Profile
- For stable interfragmentary compression
- For excellent purchase in cancellous bone

4.0 mm Screw Head Height/ 6.5 mm Screw Head Diameter
- Low profile
- Standard 3.5 mm hexagonal socket
- Can be used through the following implants:
  - 3.5 mm and 4.5 mm Reconstruction Plates
  - One-Third Tubular Plates
  - Cloverleaf Plates
  - Small T-Plates
  - 3.5 mm Dynamic Compression Plates (DCP®)
  - Spiked Washer

1.75 mm Cannulation
- Accommodates a 1.6 mm guide wire for precise screw insertion without compromising implant strength

Self-Tapping Tip
- Allows easy insertion in cancellous bone
- Simplifies technique

Reverse-Cutting Flutes
- Facilitate screw removal

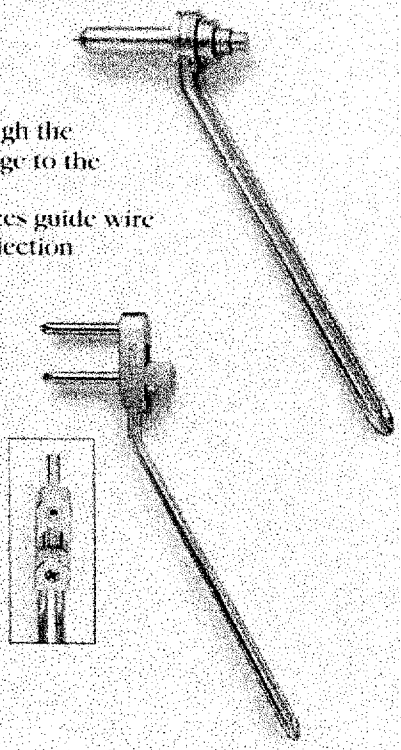
Wide Range of Screws
- For many clinical situations
- Partially or fully threaded
- Available in 20 mm–72 mm lengths

Instruments

Instruments for Percutaneous Screw Insertion
- Surgeon can perform all steps through the protection sleeve, minimizing damage to the surrounding soft tissue
- 3.2 mm/1.6 mm inner sleeve stabilizes guide wire to reduce the risk of guide wire deflection
- Allows percutaneous technique through up to 31 mm of soft tissue

Adjustable Parallel Wire Guide
- Permits multiple options for parallel placement of guide wires

1.6 mm Threaded Guide Wire
- Provides strength to minimize deflection
- Spade-point cutting tip facilitates insertion
- Brown color differentiates it from guide wires of similar diameter and length



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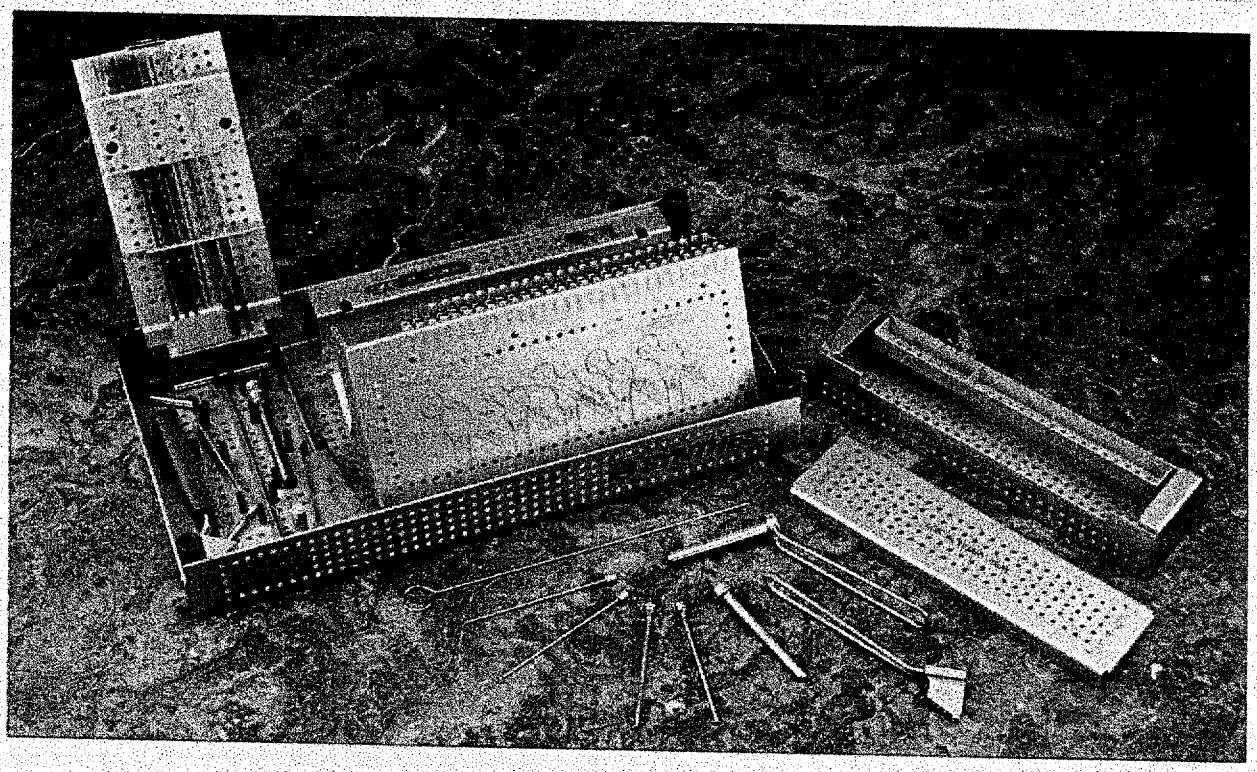
7.0 mm Cannulated Screw Set [105.07]

Designed for fixation of large bones and large bone fragments



Implant

7.0 mm Thread Diameter/ Cancellous Thread Profile
- Provides maximal resistance to pullout
- For excellent purchase and stable interfragmentary compression

8.0 mm Screw Head Diameter
- Can be used through the following implants:
  - T-Plates*
  - T-Buttress Plates*
  - L-Buttress Plates*
  - Lateral Tibial Head Buttress Plates*
  - Condylar Buttress Plates*
  - Spoon Plates*
  - Cobra Head Plates*
  - 4.5 mm Reconstruction Plates
  - 4.5 mm Broad Dynamic Compression Plates (DCP®)**
  - 4.5 mm Narrow Dynamic Compression Plates (DCP®)***

2.1 mm Cannulation
- Accommodates a 2.0 mm guide wire for precise screw insertion without compromising implant strength

Reverse-Cutting Flutes
- Facilitate screw removal, especially in dense bone

Wide Range of Screws
- For many clinical situations
- Standard 16 mm or 32 mm thread lengths; fully threaded screws are additionally available
- Available in 30 mm–150 mm lengths

*Head holes only
**Four outermost holes only
***Two outermost holes only

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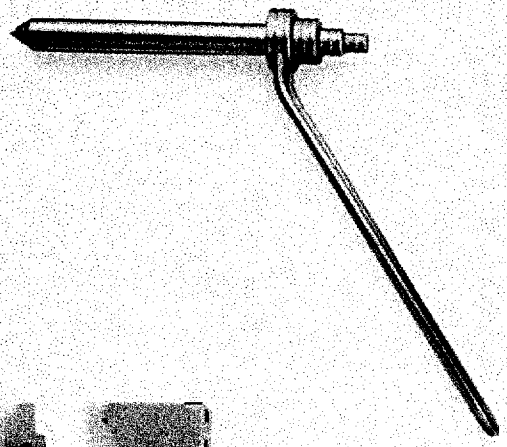
7.0 mm Cannulated Screw Set [105.07]

Instruments

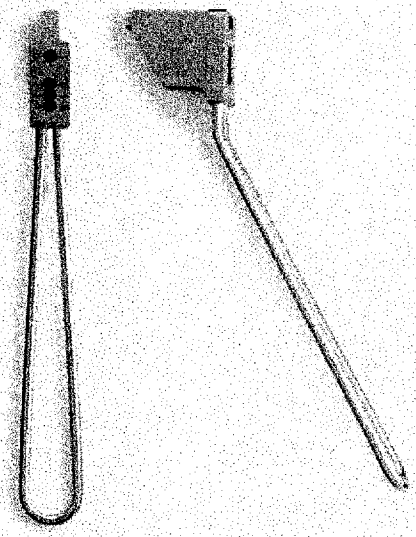
Instruments for Percutaneous Screw Insertion

- Surgeon can perform all steps through the protection sleeve, minimizing damage to the surrounding soft tissue
- 4.5 mm/2.0 mm inner sleeve stabilizes guide wire to reduce the risk of guide wire deflection
- Allows percutaneous technique through up to 90 mm of soft tissue



4.5 mm Parallel Drill Guide

- Permits multiple options for parallel placement of guide wires



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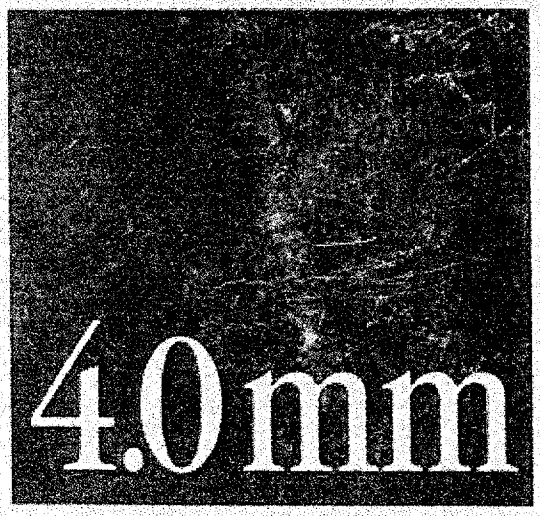
4.0 mm Cannulated Screw Set Technique Guide



An Integral Part of the SYNTHES Cannulated Screw System

SYNTHES

Original Instruments and Implants of the Association for the Study of Internal Fixation — AO/ASIF

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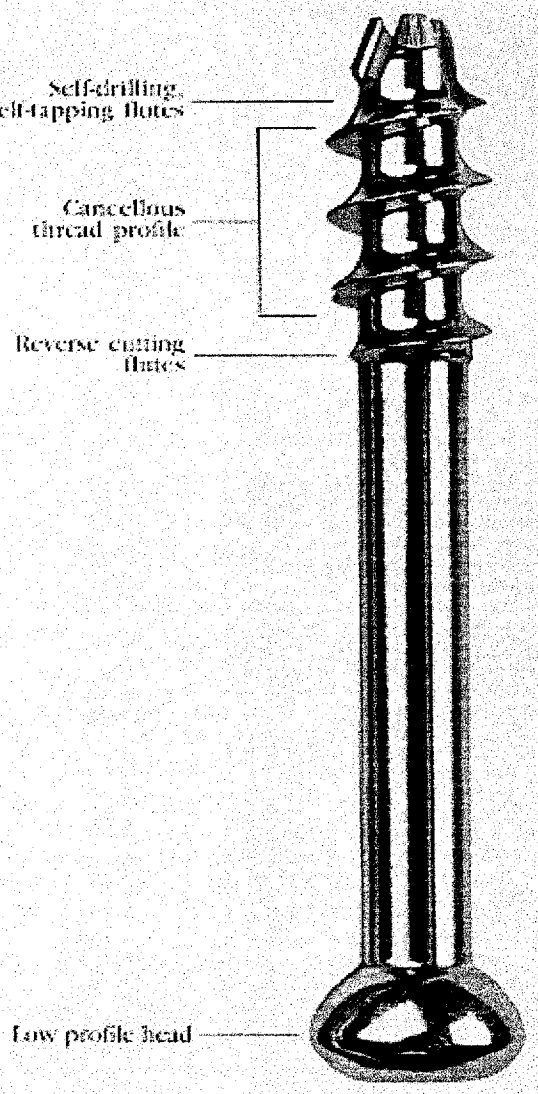
The 4.0 mm Cannulated Screw



207.610-650

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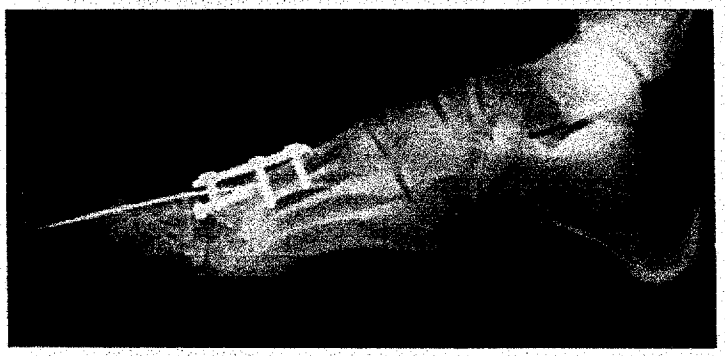
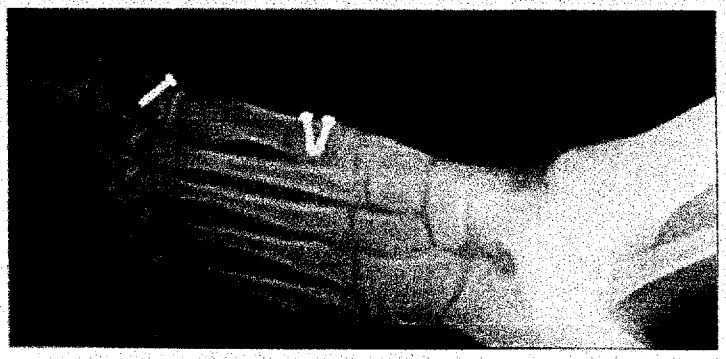
Indications

Hallux valgus corrections

- Fractures of the tarsals and metatarsals
- Metatarsal and phalangeal osteotomies
- Tarsometatarsal and metatarsophalangeal arthrodeses
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures



Metatarsophalangeal arthrodeses



Metatarsal and phalangeal osteotomies

Implant Compatability

4.0 mm Cannulated Screws can be used with the following SYNTHES implants:

- 2.7 mm L-Plates [242.31-34]
- 2.7 mm T-Plate [242.42]
- Small T-Plates [241.15-16, 241.23-25]
- Calcaneal Plates [241.61, 62 and 65]
- Cervical Vertebrae Plates [241.50-59] (when used in the foot)
- Cloverleaf Plates [241.83-86]
- Quarter-Tubular Plates [242.03-08] and [242.13-18]
- Spiked Washer [219.048]

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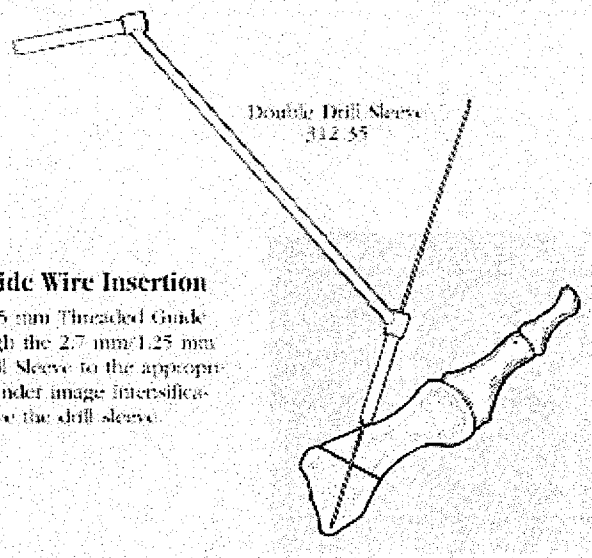
Surgical Technique

Cleaning Tip:

Cleaning the cannulation in each instrument is imperative for proper function. Instruments should be cleaned intraoperatively with the 1.25 mm Cleaning Stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire. Instruments should be cleaned postoperatively with the stylet and cleaning brush.

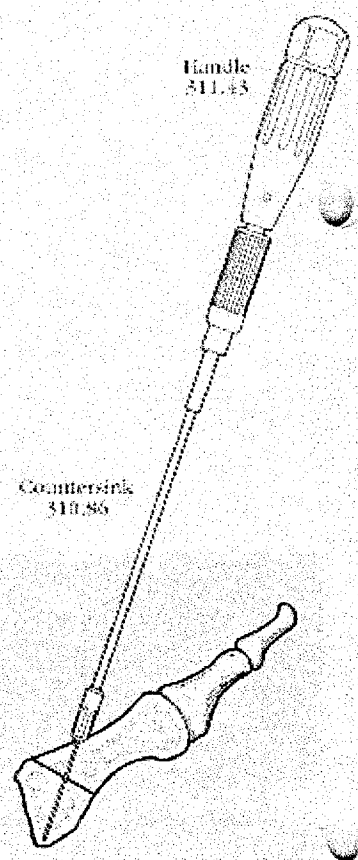
Technique Tip:

The self-drilling, self-tapping flutes of the 4.0 mm Cannulated Screw make predrilling and pretapping unnecessary in most cases. The set includes 2.7 mm Cannulated Drill Bits and a Cannulated Tap for use in dense bone, if needed.



1 Guide Wire Insertion

Insert a 1.25 mm Threaded Guide Wire through the 2.7 mm/1.25 mm Double Drill Sleeve to the appropriate depth under image intensification. Remove the drill sleeve.



2 Using the Countersink

In areas where soft tissue coverage is minimal, use the Cannulated Countersink to create a recess for the screw head. Countersinking will also facilitate screw insertion.

Note: In dense bone, if countersinking is not required, use a 2.7 mm Cannulated Drill (# 310.67) to penetrate the near cortex.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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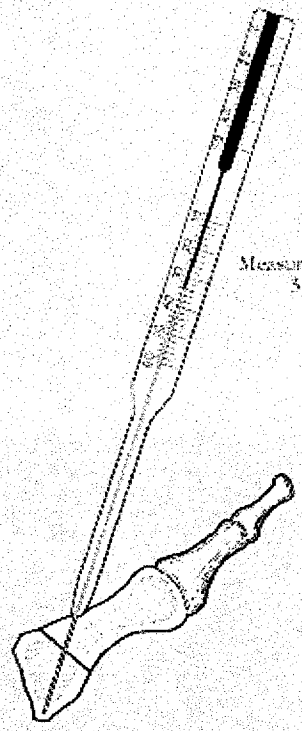
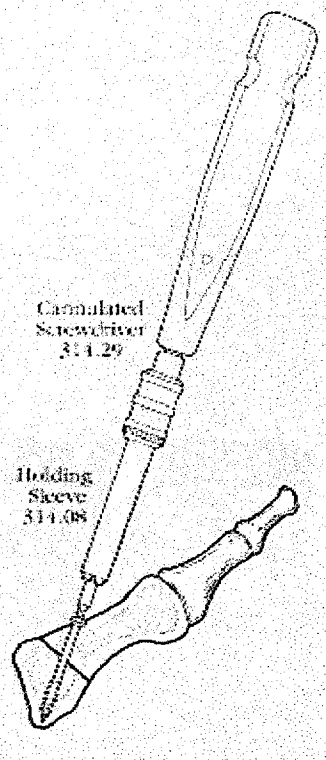
Measuring for the Screw

Slide the tapered end of the Cannulated Screw Measuring Device over the guide wire, down to the bone. This reading determines appropriate screw length, which will place the screw 5 mm short of the tip of the guide wire, allowing the threaded portion of the guide wire to remain in the bone during screw insertion.

Example: If the reading indicates 34 mm, use a 34 mm screw.





Inserting the Screw

Place the appropriate length screw over the guide wire. Use the Cannulated Hexagonal Screwdriver and Holding Sleeve to insert the screw. Remove and discard the guide wire.

Note: Power insertion of screws without use of the Holding Sleeve increases the risk of stripping the hex recess. If power insertion is preferred, use the Cannulated Hexagonal Screwdriver Shaft (314.16) and Holding Sleeve.

Note: In osteoporotic bone, a washer may be used to prevent the screw head from sinking into the bone.

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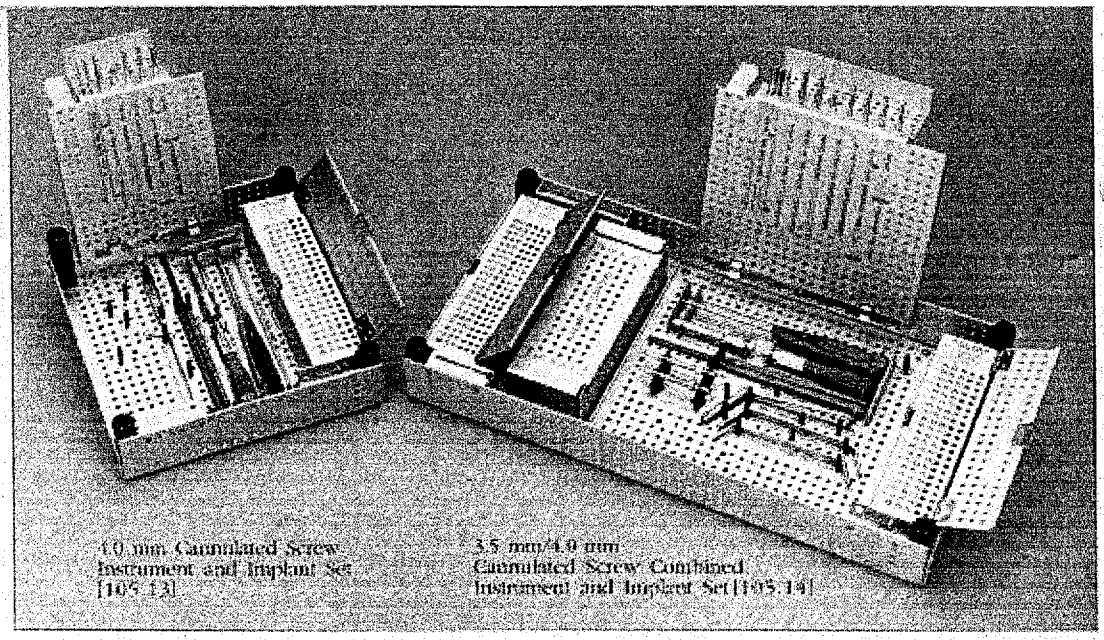


4.0 mm Cannulated Screw Instrument and Implant Set [105.13]

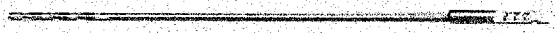
3.5 mm/4.0 mm Cannulated Screw Combined Instrument and Implant Set [105.14]

Instruments

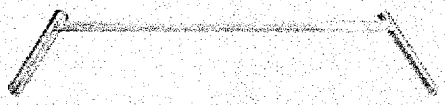
included in sets 105.13 and 105.14

1.25 mm Threaded Guide Wire [292.62] minimizes reduction during drilling. Threaded spade point tip allows easy penetration into the bone and maximum resistance to inadvertent removal. 150 mm length. 2 pkgs. of 10 ea.

Cannulated Screw Measuring Device [319.15] provides a direct reading for screw length.



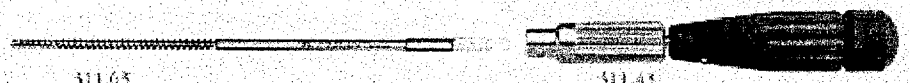
2.7 mm Cannulated Drill Bit [310.67] 140 mm/130 mm*. 1.55 mm cannulation, quick coupling. 2 ea.



2.7 mm/1.25 mm Double Drill Sleeve [312.55] protects soft tissue during guide wire placement and drilling.

310.86 311.45

Cannulated Countersink [310.86] cuts a recess for the screw head. Quick-connects to **Handle, with quick coupling** [311.45].



311.65 311.45

Cannulated Tap for 4.0 mm Cannulated Screws [311.65] allows precise tapping in dense bone when necessary. 147 mm/60 mm*. Quick-connects to **Handle, with quick coupling** [311.45].

* Total length/Effective length

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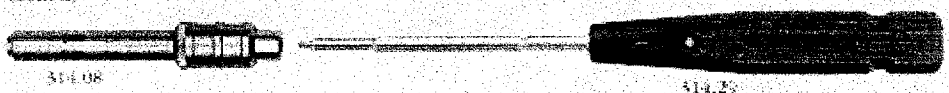
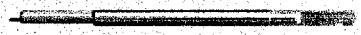
Instruments (cont'd)



314.08 314.29

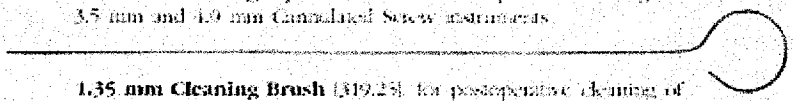
Cannulated Hexagonal Screwdriver [314.29] is fully cannulated for insertion of any 3.5 mm or 4.0 mm Cannulated Screw over the guide wire. Accommodates **Holding Sleeve** [314.08].



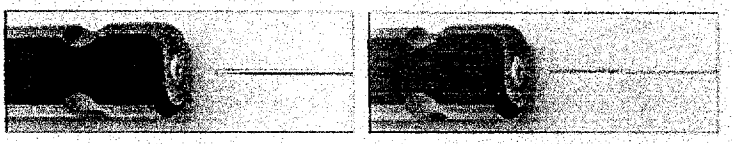
Small Hexagonal Screwdriver Shaft [314.05] is recommended for removal of 3.5 mm and 4.0 mm Cannulated Screws; connects to **Handle, with quick coupling** [311.43].

Screw Forceps [319.97]

1.25 mm Cleaning Stylet [319.38], for intraoperative cleaning of 3.5 mm and 4.0 mm Cannulated Screw instruments.



1.35 mm Cleaning Brush [319.23], for postoperative cleaning of 3.5 mm and 4.0 mm Cannulated Screw instruments.



Note: Clear instrument cannulations intraoperatively with the cleaning stylet. Clean instruments postoperatively with the stylet and the cleaning brush.

Instruments

(included in combined set 105.14)

The 3.5 mm and 4.0 mm combined set includes the instruments shown above, plus the following:

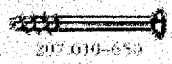
Cannulated Tap for 3.5 mm Cannulated Screws [311.99] 147 mm/60 mm*; Quick-connects to **Handle, with quick coupling** [311.43].

3.5 mm/2.7 mm Drill Guide with Stop [312.85] is used for precise drilling to a predetermined depth.

3.5 mm/2.5 mm Double Drill Sleeve [312.28] protects soft tissue.

Implants

(included in sets 105.15 and 105.14)

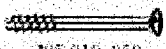


207.010–050

4.0 mm Cannulated Screws, short thread [207.010–050] 10 mm–50 mm lengths, 2 mm increments, thread length 1/3 screw length.

Washers, 7.0 mm, for small screws [219.99] to prevent screw head from sinking into osteoporotic bone, 6 ea.

(included in contained set 105.14)



205.010–050

3.5 mm Cannulated Screws, partially threaded [205.010–050] 10 mm–50 mm lengths, 2 mm increments.

* Total length/effective length.

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Set Contents

4.0 mm Cannulated Screw Instrument and Implant Set
[105.13]

304.310	4.0 mm Cannulated Screw Instrument and Implant Set Graphic Case
207.610 – 207.650	4.0 mm Cannulated Screws, short thread, 10 mm–50 mm*, 5 ea.
219.98	Washer, 6 ea.
292.62	1.25 mm Threaded Guide Wire, 150 mm, 2 pkgs. of 10
310.67	2.7 mm Cannulated Drill Bit, 2 ea.
310.86	Cannulated Countersink
311.43	Handle, with quick coupling
311.63	Cannulated Tap for 4.0 mm Cannulated Screws
312.35	2.7 mm/1.25 mm Double Drill Sleeve
314.03	Small Hexagonal Screwdriver Shaft
314.08	Holding Sleeve
314.29	Cannulated Hexagonal Screwdriver
319.15	Cannulated Screw Measuring Device
319.25	1.35 mm Cleaning Brush
319.38	1.25 mm Cleaning Stylet
319.97	Screw Forceps

3.5 mm/4.0 mm Cannulated Screw Combined Instrument and Implant Set
[105.14]

304.300	3.5 mm/4.0 mm Cannulated Screw Combined Instrument and Implant Set Graphic Case

The 3.5 mm/4.0 mm combined set includes all instruments and implants listed above, plus the following:

205.010 – 205.050	3.5 mm Cannulated Screws, partially threaded, 10 mm–50 mm*, 5 ea.
311.39	Cannulated Tap for 3.5 mm Cannulated Screws
312.28	3.5 mm/2.5 mm Double Drill Sleeve
312.85	3.5 mm/2.7 mm Drill Handle with Stop

Additionally Available Implants

3.5 mm Cannulated Screws, fully threaded [105.210–250] 10 mm–50 mm lengths, 2 mm* increments

4.0 mm Cannulated Screws, long thread [207.710–750] 16 mm–50 mm lengths, 2 mm* increments. Thread length 1/2 screw length

Recommended Additional Instruments

310.68	3.5 mm Cannulated Drill Bit, 100 mm/130 mm*, 1.35 mm cannulation, quick coupling
314.10	Cannulated Hexagonal Screwdriver Shaft allows power insertion of 3.5 mm and 4.0 mm Cannulated Screws, connects to Small Air Drill [511.10 or 511.11].
511.10 or 511.11	Small Air Drill

* 2.0 mm increments
* Total length/thread length

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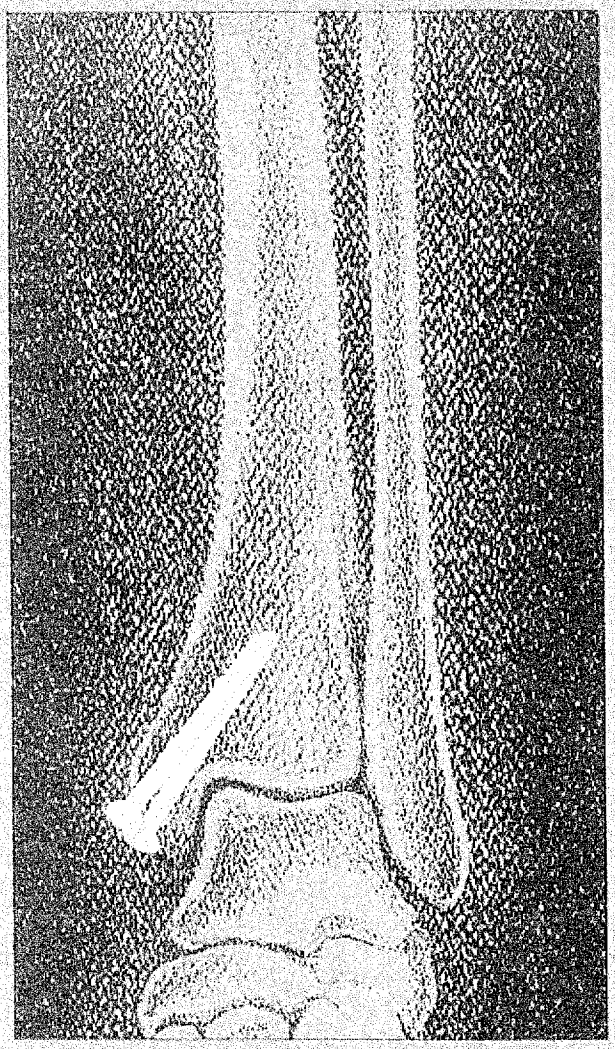
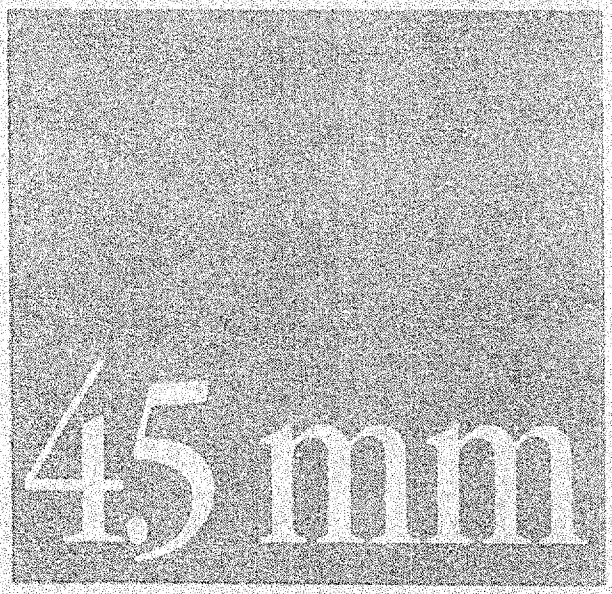


4.5 mm Cannulated Screw Set Technique Guide

- Self-Tapping Screw
- Cancellous Thread Profile
- Simple, Precise Instrumentation



Part of the SYNTHES Cannulated Screw System

SYNTHES

Original Instruments and Implants of the Association for the Study of Internal Fixation – AO/ASIF

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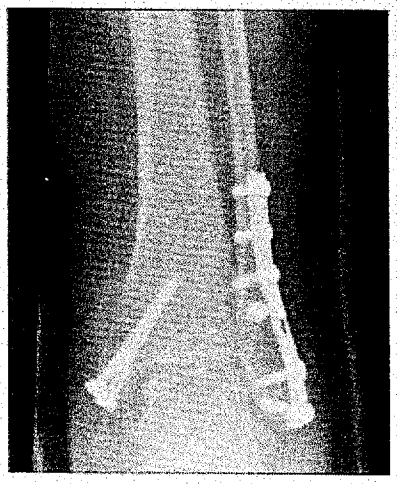
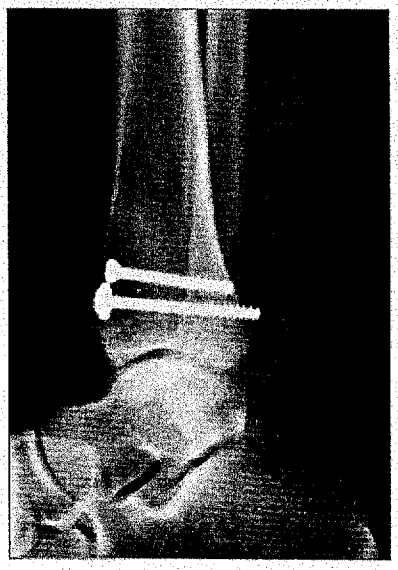
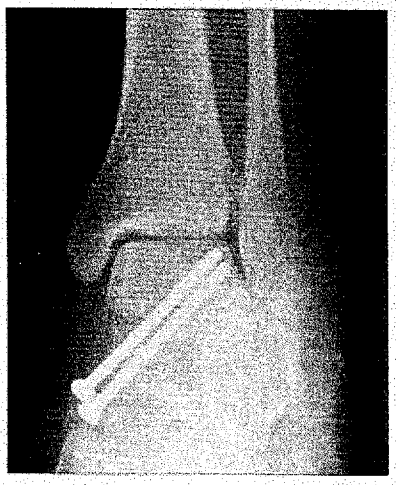
Indications



Malleolar fractures



Pilon fractures



Fractures of the calcaneus and talus

Intermediate-sized fragments in fractures, such as:

- Malleolar and pilon fractures
- Acetabular and pelvic fractures
- Fractures of the calcaneus and talus
- Fractures of the proximal and distal humerus
- Patellar fractures
- Certain tibial plateau fractures

Also:

- Arthrodeses of the tarsals
- Ligament fixation of the proximal humerus

Implant Compatibility

4.5 mm Cannulated Screws can be used through the following SYNTHES implants:

- 3.5 mm Reconstruction Plates [245.00–19]
- One-Third Tubular Plates [241.02–12]
- Cloverleaf Plates [240.23 & 24, .205–208]
- 3.5 mm Dynamic Compression Plates (DCP®) [248.02–22]
- 4.5 mm Reconstruction Plates [229.33–46]
- Small T-Plates [241.13–16, .23–25]
- Spiked Washer [219.955]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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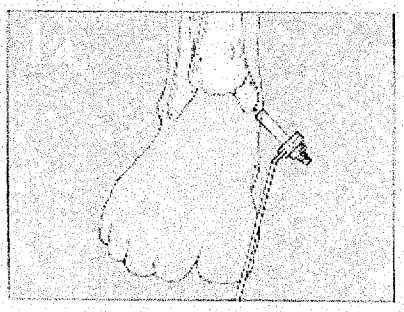
Techniques

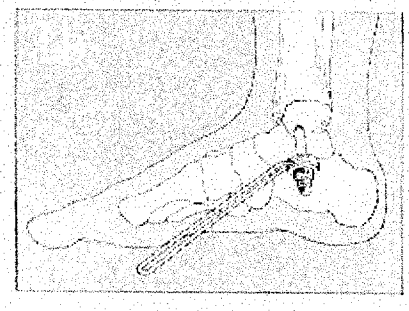
General Technique Tips:

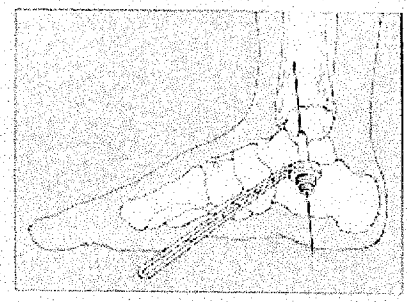
- Reduce and hold bone fragments in position with Kirschner wires or forceps prior to placing guide wires.
- Because of their hollow cross section and long length, cannulated drill bits are more susceptible to breakage than solid drill bits of the same diameter. Use less axial force, avoid bending, and advance the drill bit slowly to minimize the possibility of breakage. Cannulated drill bits should be inspected after every procedure and replaced if worn or damaged.
- **Cleaning of the cannulation in each instrument is imperative for proper function.** Instruments should be cleaned intraoperatively with the 1.6 mm Cleaning Stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire. Instruments should be cleaned postoperatively with the stylet and the cleaning brush (additionally available).



Percutaneous Insertion of Screws

Make a stab incision and bluntly dissect as needed to the bone. Insert the Percutaneous Sleeve Assembly (9.5 mm/7.0 mm Protection Sleeve, 7.0 mm/3.2 mm and 3.2 mm/1.6 mm Drill Sleeves, and 1.6 mm Trocar) through the soft tissue to the near cortex.

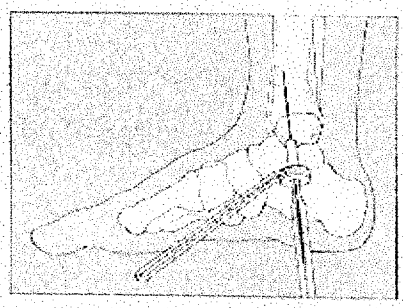




Remove the trocar and insert a 1.6 mm Threaded Guide Wire through the innermost drill sleeve to the appropriate depth under image intensification.

Additional parallel guide wires may be placed using the Adjustable Parallel Wire Guide. (See technique, next page.)

Technique tip: Run the drill at maximum speed to minimize deflection while gradually advancing the guide wire.



Remove the two inner drill sleeves. Slide the tapered end of the Cannulated Screw Measuring Device over the guide wire through the protection sleeve. This reading determines appropriate screw length. Select a 4.5 mm Cannulated Screw of this length and set it aside.

Note: Screw length will be 5 mm short of the guide wire tip (the length of the threaded portion of the wire), preventing penetration of the far cortex.

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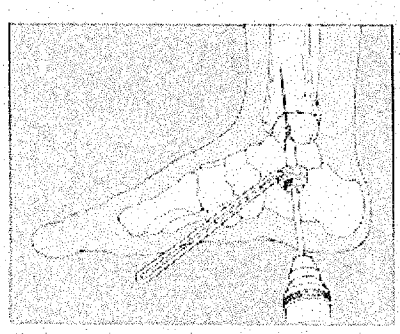
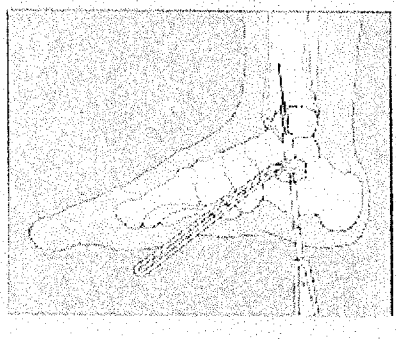
Techniques



Place the 7.0 mm/3.2 mm Drill Sleeve into the protection sleeve, and drill through the near cortex with the 3.2 mm Cannulated Drill Bit. Remove the 7.0 mm/3.2 mm Drill Sleeve.

Technique tip: In dense bone or in certain fracture patterns, the surgeon may choose to drill the entire length of the screw. The drill guide with stop [312.85] with 3.5 mm insert (from the 3.5 mm Cannulated Screw Set) may be used with the calibrated slot on the back of the measuring device for the 4.5 mm Cannulated Screw to preset and control drilling depth. Set the drilling depth to the previously measured screw length. Always confirm drilling depth under image intensification.

Technique tip: Avoid directing the drill bit; let it follow the guide wire. Take care to remove the drill bit slowly and to pull back straight while running the drill forward to prevent guide wire pullout.

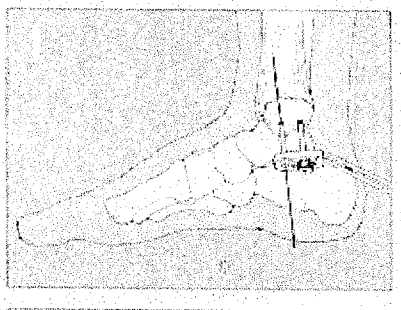


(Optional) In very dense bone use the cannulated tap through the protection sleeve to prepare for screw insertion. Where necessary, use the Cannulated Countersink to create a recess for the screw head.

Using the Cannulated Hexagonal Screwdriver without the Holding Sleeve, insert the previously selected screw (step 3) through the protection sleeve. Remove and discard the guide wire.

Note: In osteoporotic bone, a washer may be used to prevent the screw head from sinking into bone. Washers cannot be placed through the protection sleeve. Remove the sleeve prior to placing the washer over the guide wire.

Insertion of Parallel Wires



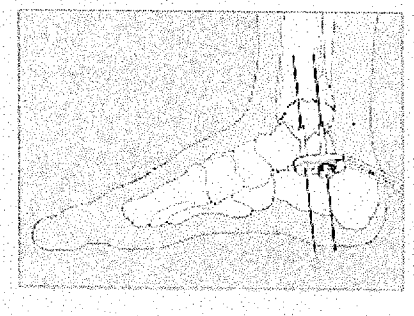
Remove all sleeves from over the first guide wire. Place the fixed sleeve on the Adjustable Parallel Wire Guide over the previously placed wire.

Adjust the movable sleeve to the desired position and tighten the knurled nut. Insert a guide wire through the adjustable drill sleeve. Insert any additional guide wires following the same procedure.

Note: A separate incision may be needed.

Note: Any previously inserted guide wire can be used in the fixed sleeve of the guide for parallel placement of the next guide wire.

Technique tip: Avoid placing any bending forces on the first guide wire, as this will affect parallelism.



Remove the instruments, and place the protection sleeve and two inner drill sleeves over one of the guide wires. Insert screws following the screw insertion technique (see previous page, steps 3–5).

Note: To prevent loss of reduction, drill and insert each screw before proceeding to the next screw.

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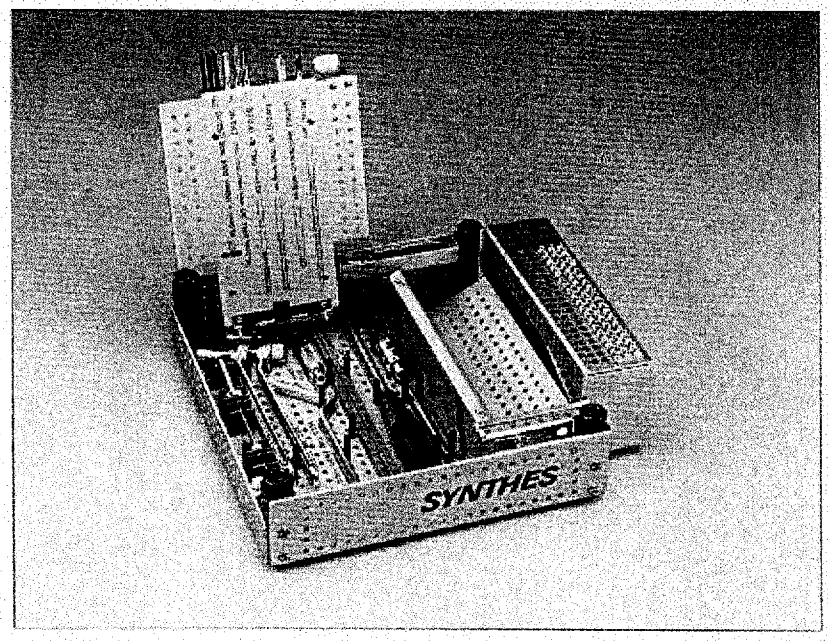
105.04 4.5 mm Cannulated Screw Instrument and Implant Set

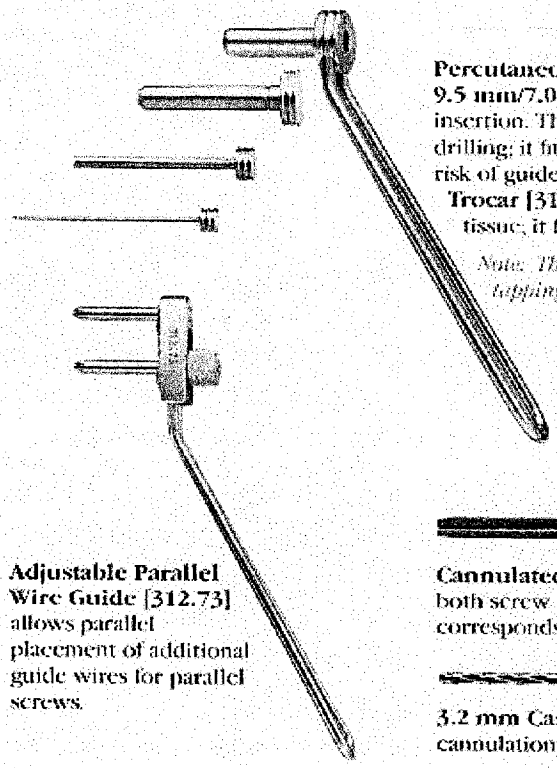
Set Contents

Instruments



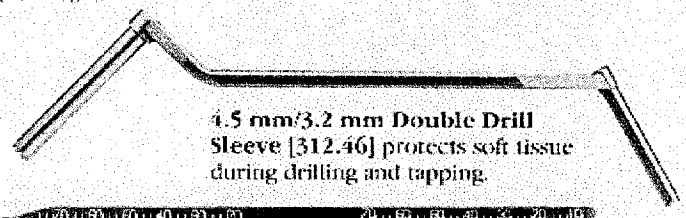
Graphic Case [304.220]

1.6 mm Threaded Guide Wire [292.72] maintains reduction during drilling. Threaded spade point tip allows easy penetration into the bone and maximum resistance to inadvertent removal. Brown color helps differentiate it from other guide wires and K-wires of similar diameter and length. 150 mm, 10 ea.



Percutaneous Sleeve Assembly: All steps can be performed through the **9.5 mm/7.0 mm Protection Sleeve [312.77]**, including measuring and screw insertion. The **7.0 mm/3.2 mm Drill Sleeve [312.76]** is used to protect while drilling; it fits 312.77. The **3.2 mm/1.6 mm Drill Sleeve [312.75]** reduces the risk of guide wire deflection during insertion; it fits 312.76. The **1.6 mm Trocar [312.74]** facilitates passage of the sleeve assembly through the soft tissue; it fits 312.75.

Note: These instruments can be used as protection sleeves for drilling and tapping during open surgery.



4.5 mm/3.2 mm Double Drill Sleeve [312.46] protects soft tissue during drilling and tapping.

Cannulated Screw Measuring Device [319.17] provides a direct reading for both screw length and maximum drilling depth. Light brown color corresponds to the color of the guide wire.

Adjustable Parallel Wire Guide [312.73] allows parallel placement of additional guide wires for parallel screws.

3.2 mm Cannulated Drill Bit [310.65] 170 mm/140 mm*, 1.75 mm cannulation, quick coupling, 2 ea.

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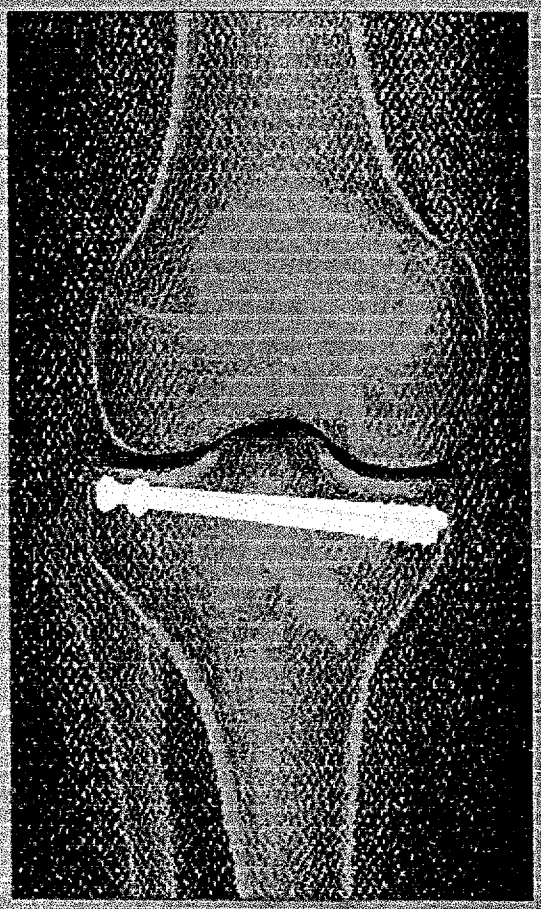

7.0 mm Cannulated Screw Set Technique Guide

- Large Thread Diameter
- Reverse-Cutting Flutes
- Simple, Precise Instrumentation

Part of the SYNTHES Cannulated Screw System

7.0 mm

SYNTHES

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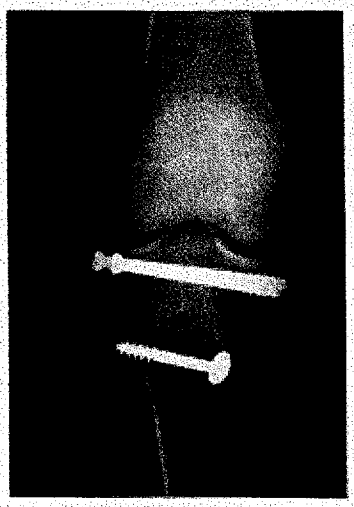
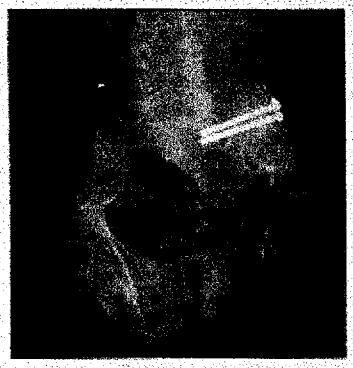
Indications

Intracapsular fractures of the hip



Tibial plateau fractures



Sacroiliac joint disruptions

Large fragments in fractures, such as:

- Intracapsular fractures of the hip
- Tibial plateau fractures
- Pediatric femoral neck fractures
- Femoral intercondylar fractures

Also:

- Sacroiliac joint disruptions
- Ankle arthrodeses
- Slipped capital femoral epiphyses

Implant Compatability

7.0 mm Cannulated Screws can be used through the following SYNTHES implants:

- T-Plates* [240.13–18]
- T-Buttress Plates* [240.34–36, .307–309]
- L-Buttress Plates* [240.44 & 54, .405–409, .505–509]
- Lateral Tibial Head Buttress Plates* [240.46–50, .56–60]
- Condylar Buttress Plates* [240.70–75, .92–95]
- Spoon Plates* [240.05 & 06]
- Cobra Head Plates* [240.90, 91, 98 & 99]
- 4.5 mm Reconstruction Plates [229.33–46]
- 4.5 mm Broad Dynamic Compression Plates (DCP®)** [226.06–26]
- 4.5 mm Narrow Dynamic Compression Plates (DCP®)*** [224.02–24]

* Head holes only
** Four outermost holes only
*** Two outermost holes only

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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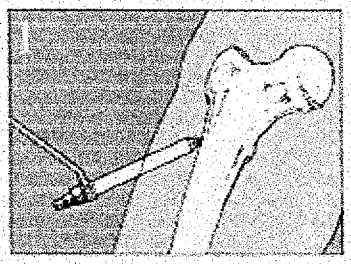
Techniques

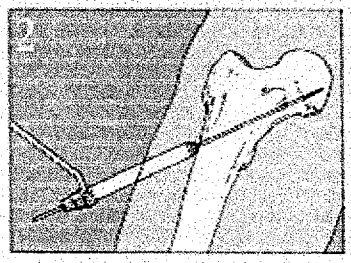
General Technique Tips:

- Because of their hollow cross section and long length, cannulated drill bits are more susceptible to breakage than solid drill bits of the same diameter. Use less axial force, avoid bending, and advance the drill bit slowly to minimize the possibility of breakage. Cannulated drill bits should be inspected after every procedure and replaced if worn or damaged.
- **Cleaning of the cannulation in each instrument is imperative for proper function.** Instruments should be cleaned intraoperatively with the 2.0 mm Cleaning Stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire. Instruments should be cleaned postoperatively with the stylet and the cleaning brush (additionally available).



Percutaneous Insertion of Screws

1 (If necessary, for fixation of femoral neck fractures, insert an anteversion wire according to normal AO technique.) Make a stab incision and bluntly dissect as needed to the bone. Insert the Percutaneous Sleeve Assembly (11.0 mm/8.0 mm Protection Sleeve, 8.0 mm/4.5 mm and 4.5 mm/2.0 mm Drill Sleeves, and 2.0 mm Trocar) through the soft tissue to the near cortex. Confirm under image intensification.

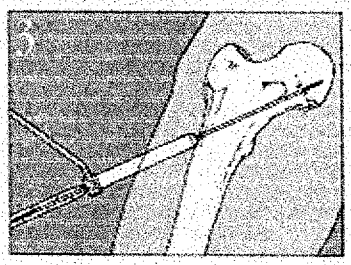


2 Remove the trocar and insert a 2.0 mm Threaded Guide Wire through the innermost drill sleeve to the appropriate depth under image intensification. Confirm wire placement in the A-P and lateral views.

Additional parallel guide wires may be placed percutaneously using the 4.5 mm Parallel Drill Guide. (See technique for the parallel drill guide, next page.)

Technique tip: To prevent slippage, the 4.5 mm/2.0 mm Drill Sleeve may be tapped with a hammer to seat the teeth in the lateral surface.

Technique tip: Run the drill at maximum speed to minimize deflection while gradually advancing the guide wire.



3 Remove the two inner drill sleeves. Slide the tapered end of the Cannulated Screw Measuring Device over the guide wire. This reading determines appropriate screw length. Select a 7.0 mm Cannulated Screw of this length, with a thread which engages only the opposite fragment, and set it aside.

Note: Screw length will be 8 mm short of the guide wire tip (the length of the threaded portion of the wire), preventing penetration of the far cortex.

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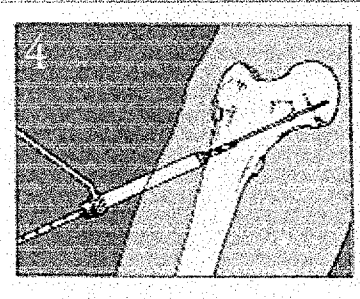
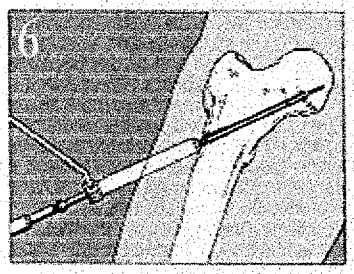


4 Place the 8.0 mm/4.5 mm Drill Sleeve into the protection sleeve, and drill with the 4.5 mm Cannulated Drill Bit under image intensification to the appropriate depth, being careful not to drill over the guide wire threads and penetrate the far cortex. Remove the 8.0 mm/4.5 mm Drill Sleeve.

Technique tip: Avoid directing the drill bit; let it follow the guide wire. Take care to remove the drill bit slowly and to pull back straight while moving the drill forward to prevent guide wire pullout.

Note: Depending on bone quality, the surgeon may choose to drill only the near cortex to prevent inadvertent guide wire pullout.

Note: The calibrations on the cannulated drill bits and the cannulated tap are not accurate when using the percutaneous sleeves. Use image intensification for confirmation of drilling and tapping depths.



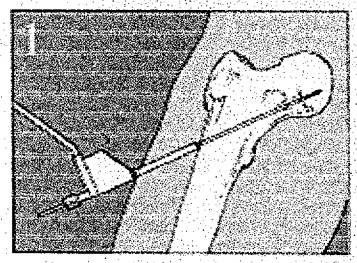
5 Where necessary, tap the near cortex with the cannulated tap through the protection sleeve. In dense bone, it may be necessary to tap over the entire nonthreaded length of the guide wire.

6 Using the Cannulated Hexagonal Screwdriver without the Holding Sleeve, insert the previously selected screw (step 3) through the protection sleeve. Remove and discard the guide wire.

Note: In osteoporotic bone, use a washer to prevent the screw head from sinking into bone. Washers cannot be placed through the percutaneous sleeve. Remove the sleeve prior to placing the washer over the guide wire.

Insertion of Parallel Wires

For the management of femoral neck fractures, three parallel screws are placed. There are two methods for placing parallel guide wires: with the 4.5 mm Parallel Drill Guide [319.30] or the Parallel Wire Guide [312.71]. For percutaneous placement of screws, the parallel drill guide should be used.



1. 4.5 mm Parallel Drill Guide [319.30]

1 If inserting screws percutaneously, remove all sleeves from over the first guide wire (placed in step 2 on previous page). Insert one 4.5 mm/2.0 mm Drill Sleeve into the outermost 4.5 mm hole of the parallel drill guide. Place this combination over the guide wire and push directly to the bone.

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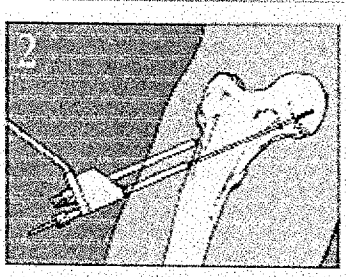
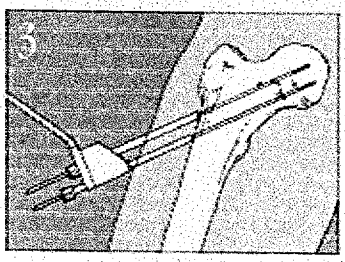
Techniques



2 Insert a second 4.5 mm/2.0 mm Drill Sleeve and the 2.0 mm Trocar into any of the other three holes in the parallel drill guide. Press the trocar to the near cortex.

Note: Possible distances between parallel guide wires are 10 mm, 14 mm and 18 mm, measured from the center of the primary hole of the parallel drill guide to the centers of the other holes. Plan placement of each guide wire based on these distances.



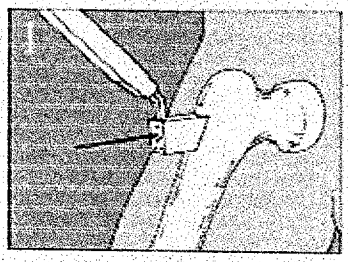
3 Remove the trocar and insert a guide wire through the 4.5 mm/2.0 mm Drill Sleeve. Insert any additional guide wires following the same procedure.

Technique tip: Avoid placing any bending forces on the first guide wire, as this will affect parallelism.

Note: Any previously inserted guide wire can be used in the outermost hole of the guide for parallel placement of the next guide wire.

4 Remove the instruments and place the 11.0 mm/8.0 mm Protection Sleeve over one of the guide wires. Insert screws following the screw insertion technique (see page 3, steps 3–6).

Note: To prevent loss of reduction, drill, tap and insert each screw before proceeding to the next screw.

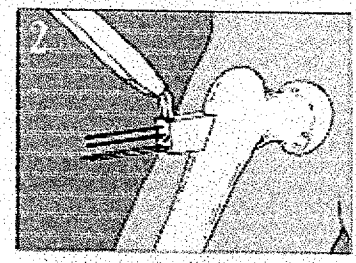


II. Parallel Wire Guide [312.71] (Open Technique)

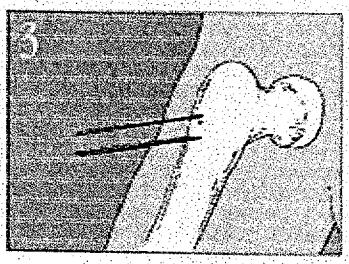
1 Place a positioning guide wire in the center of the femoral neck. Place the Parallel Wire Guide over the guide wire through one of the central diamond-patterned positioning holes.

Note: The parallel guide's position may be adjusted by replacing it over the guide wire through one of the adjacent positioning holes of the central diamond pattern.

Note: The parallel guide does not need to lie flush with the bone.



2 Under image intensification, insert a guide wire to the desired depth through each of the outer triangle-patterned placement holes.



3 Remove the parallel guide and the positioning guide wire (inserted in step 1).

4 Measure, drill, tap and insert each screw before proceeding to the next to prevent loss of reduction.

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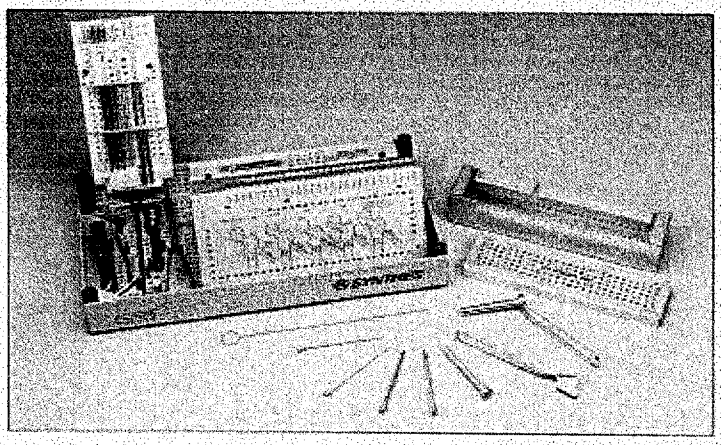
105.07 7.0 mm Cannulated Screw Instrument and Implant Set

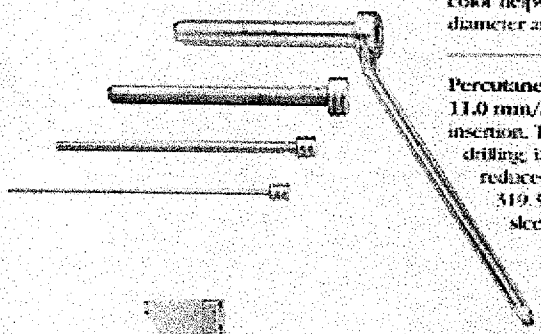
Set Contents

Instruments

Graphic Case [306.15] shows step-by-step technique and provides organization for inventory control.



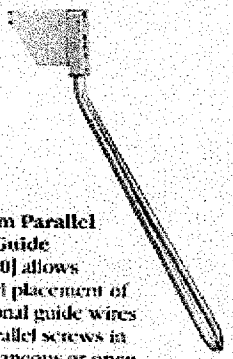
2.0 mm Threaded Guide Wire [292.65] offers strength with minimal bone removal and maintains reduction during drilling. Threaded spade point tip allows easy penetration into the bone and helps prevent pullout. Dark blue color helps differentiate it from other guide wires and K-wires of similar diameter and length. 230 mm length, 10 ea.



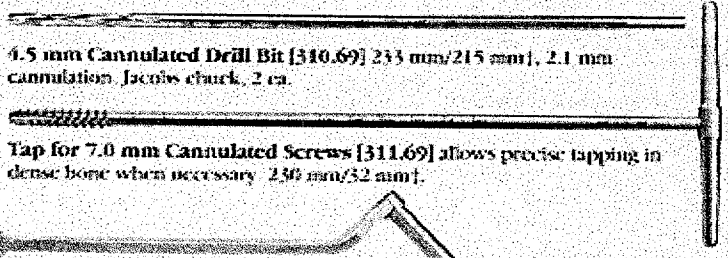
Percutaneous Sleeve Assembly: All steps can be performed through the **11.0 mm/8.0 mm Protection Sleeve [319.34]**, including measuring and screw insertion. The **8.0 mm/4.5 mm Drill Sleeve [319.33]** is used to protect while drilling; it fits 319.34. The **4.5 mm/2.0 mm Drill Sleeve [319.32]** (2 ea.) reduces the risk of guide wire deflection during surgery; it fits 319.33 and 319.30. The **2.0 mm Trocar [319.31]** (2 ea.) facilitates passage of the sleeve assembly through the soft tissue; it fits 319.32.

Note: These instruments can be used as protection sleeves for drilling and tapping during open surgery.

Cannulated Screw Measuring Device [319.21] provides a direct reading of both screw length and maximum drilling depth. Light blue color corresponds to the color of the guide wire.

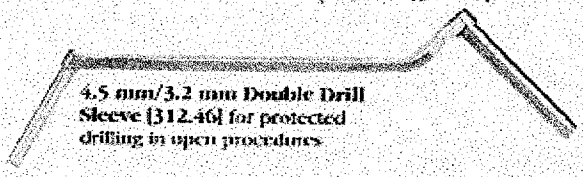


4.5 mm Parallel Drill Guide [319.30] allows parallel placement of additional guide wires for parallel screws in percutaneous or open procedures.



4.5 mm Cannulated Drill Bit [310.69] 233 mm/215 mm], 2.1 mm cannulation. Jacobs chuck, 2 ea.

Tap for 7.0 mm Cannulated Screws [311.69] allows precise tapping in dense bone when necessary. 230 mm/32 mm].



4.5 mm/3.2 mm Double Drill Sleeve [312.46] for protected drilling in open procedures.

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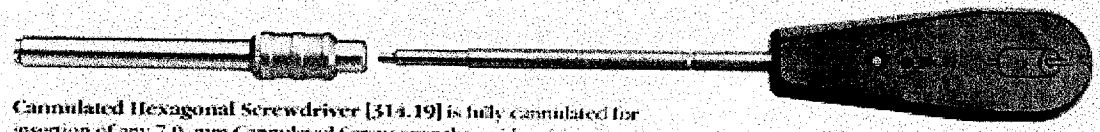
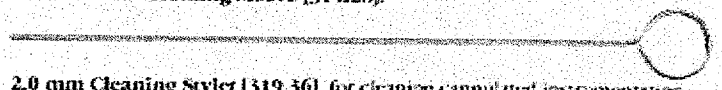
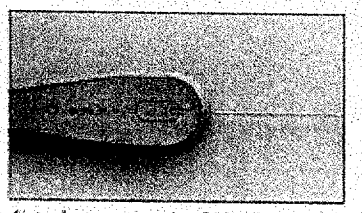
105.07 7.0 mm Cannulated Screw Instrument and Implant Set



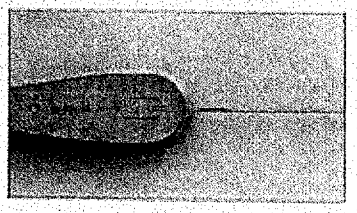
Cannulated Hexagonal Screwdriver [314.19] is fully cannulated for insertion of any 7.0 mm Cannulated Screw over the guide wire. Accommodates **Holding Sleeve [314.28]**.



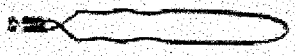
2.0 mm Cleaning Stylet [319.36], for cleaning cannulated instrumentation.



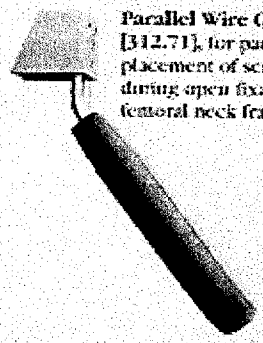
Note: Instruments should be cleaned intraoperatively with the 2.0 mm Cleaning Stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire. Instruments should be cleaned postoperatively with the stylet and the cleaning brush (additionally available).



2.0 mm Drill Bit [310.19], for predrilling the guide wire. 100 mm/75 mm†, quick coupling, 2 ea.

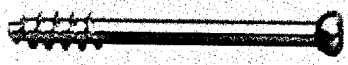


Screw Forceps [319.97]



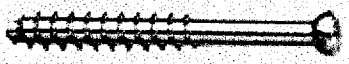
Parallel Wire Guide [312.71], for parallel placement of screws during open fixation of femoral neck fractures

Implants



7.0 mm Cannulated Screws, 16 mm thread length:

208.050–065 50 mm–65 mm†, 2 ea.
208.070–100 70 mm–100 mm††, 4 ea.
208.105–150 105 mm–150 mm†, 2 ea.



7.0 mm Cannulated Screws, 32 mm thread length:

209.015–065 65 mm–65 mm††, 1 ea.
209.070–100 70 mm–100 mm††, 2 ea.
209.105–130 105 mm–130 mm††, 1 ea.

Washers, 13.0 mm [219.99], to prevent screw head from sinking into osteoporotic bone, 6 ea.

Additionally Available Implants

7.0 mm Cannulated Screws, fully threaded:

209.420–530 20 mm–130 mm††

Recommended Additional Instruments

319.27 2.1 mm Cleaning Brush for use with 7.0 mm Cannulated Screw instruments

314.27 Large Hexagonal Screwdriver, for removal of cannulated screws

† total length/effective length
†† 5 mm increments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Telephone: 215-647-9700
Fax: 215-647-5347
To order: 1-800-523-0322

SYNTHES (CANADA) LTD.
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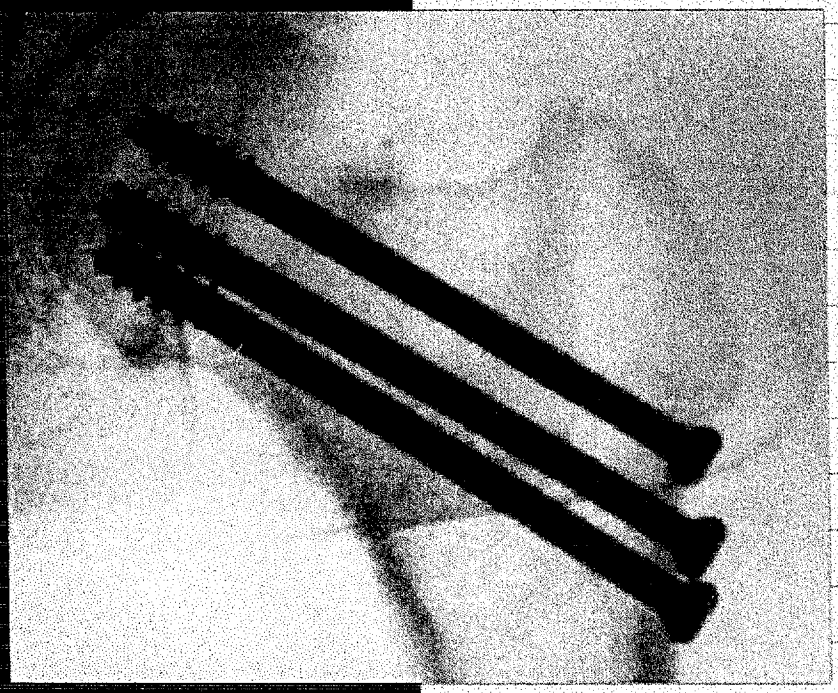
7.3 mm Cannulated Screw Technique Guide



An Integral Part of the SYNTHES Stainless Steel and Titanium Cannulated Screw System

7.3mm

SYNTHES

Original Instruments and Implants of the Association for the Study of Internal Fixation—AO/ASIF

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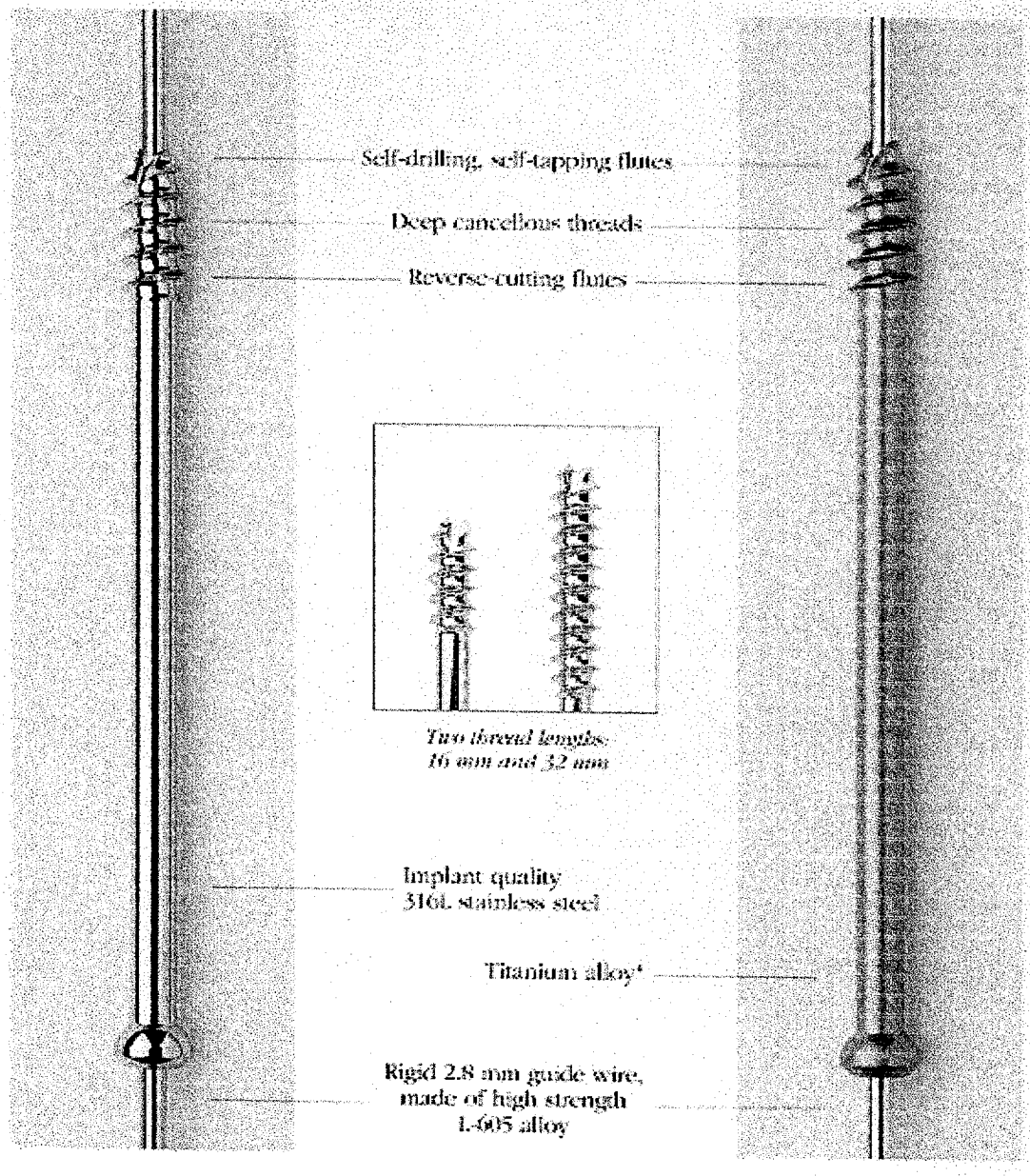
The 7.3 mm Self-drilling, Self-tapping Cannulated Screw



*Ti-6Al-7Nb

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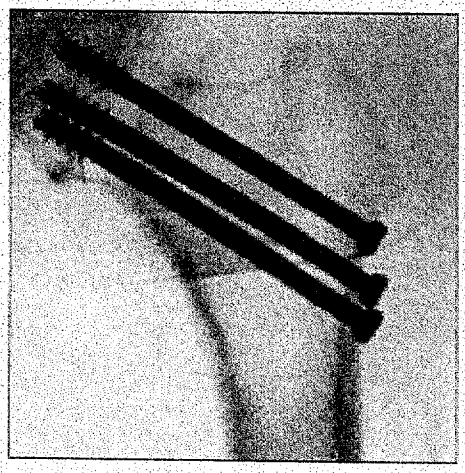
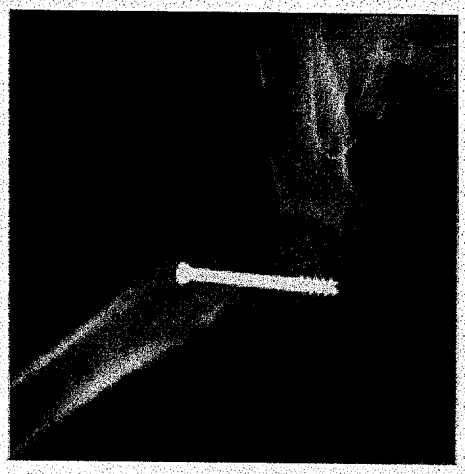
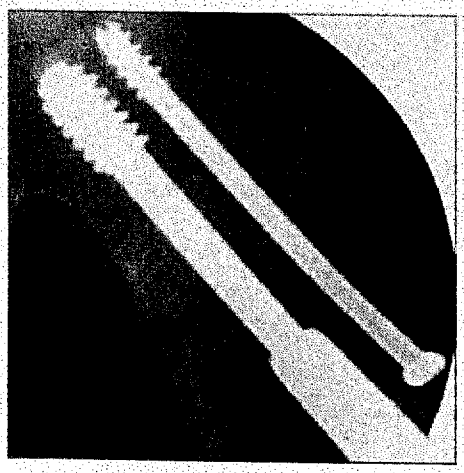
Indications



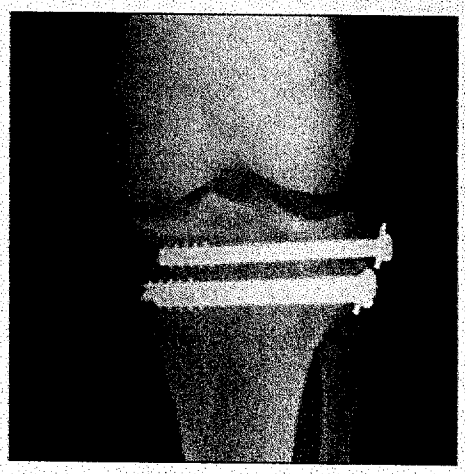
Femoral neck fractures



Slipped capital femoral epiphyses



As an adjunct to DHS® in basilar neck fractures



Tibial plateau fractures

Other indications include:

- Ankle arthrodeses
- Pediatric femoral neck fractures
- Intercondylar femur fractures
- Sacroiliac joint disruptions
- Subtalar arthrodeses

Titanium screws may be used with the Titanium Unreamed Femoral Nail system.

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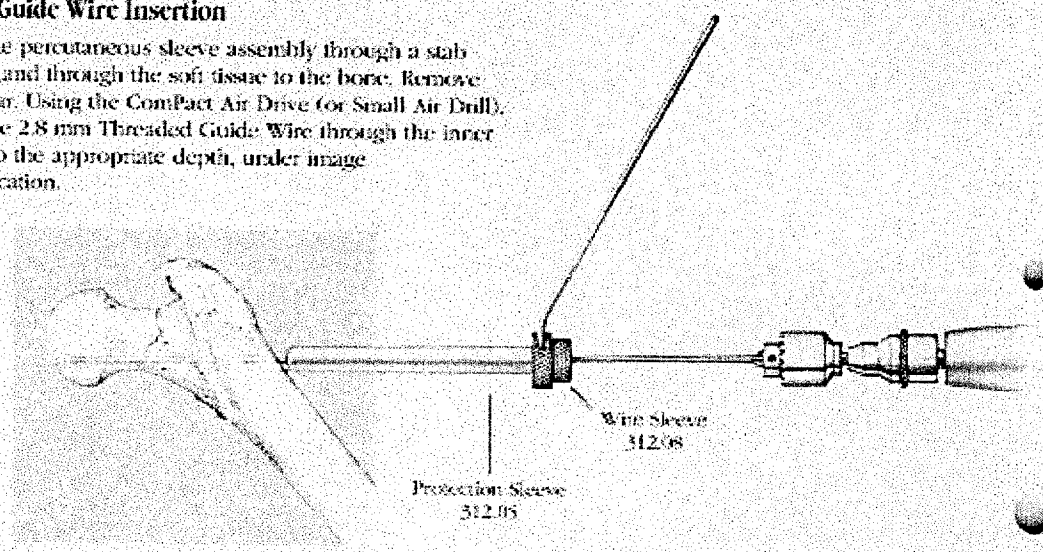
Surgical Techniques

Percutaneous Technique

1 Guide Wire Insertion

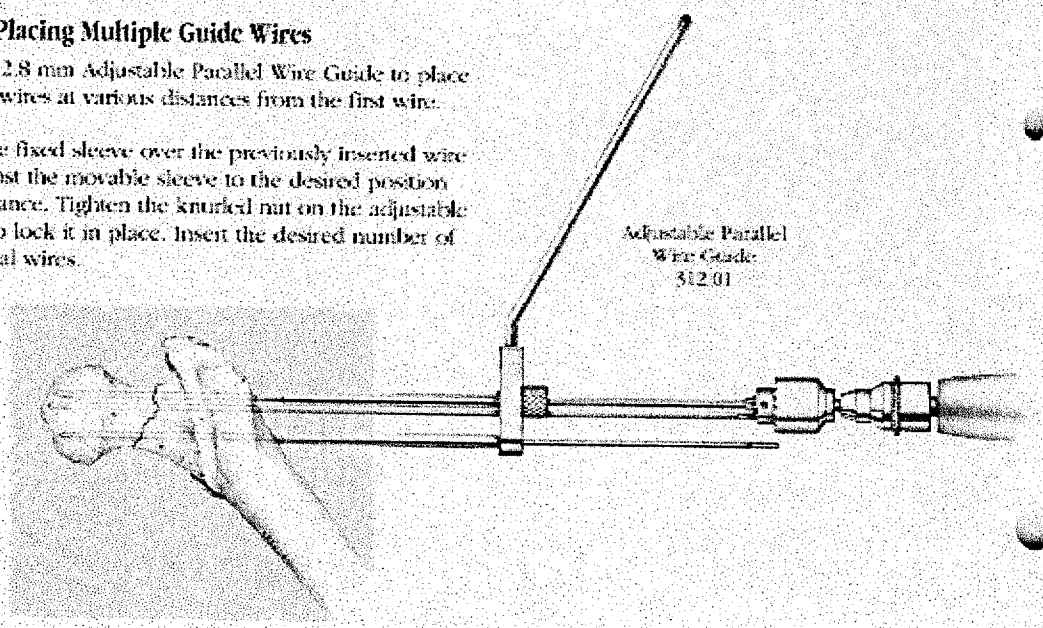
Insert the percutaneous sleeve assembly through a stab incision and through the soft tissue to the bone. Remove the trocar. Using the ComPact Air Drive (or Small Air Drill), insert the 2.8 mm Threaded Guide Wire through the inner sleeve to the appropriate depth, under image intensification.



2 Placing Multiple Guide Wires

Use the 2.8 mm Adjustable Parallel Wire Guide to place parallel wires at various distances from the first wire.

Place the fixed sleeve over the previously inserted wire and adjust the movable sleeve to the desired position and distance. Tighten the knurled nut on the adjustable sleeve to lock it in place. Insert the desired number of additional wires.



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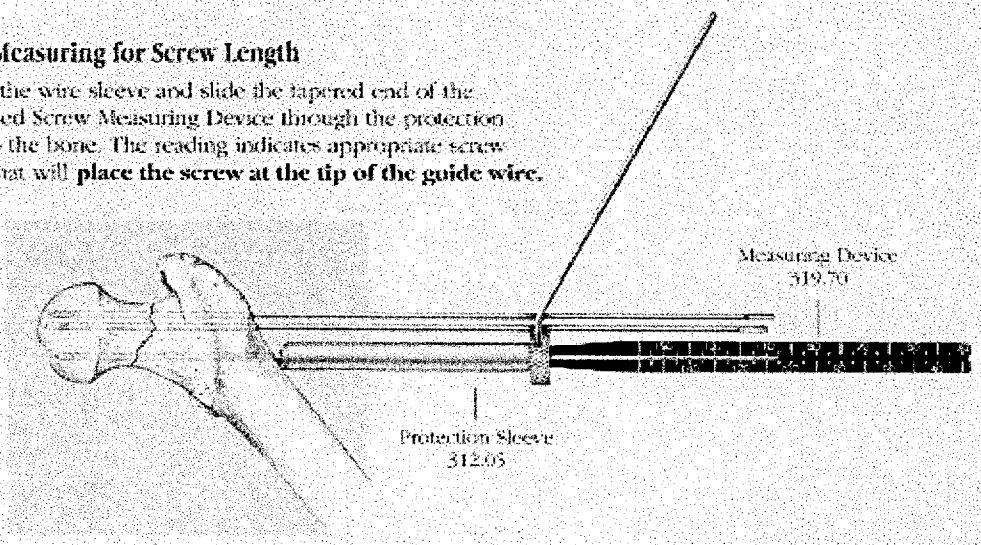
3 Measuring for Screw Length

Remove the wire sleeve and slide the tapered end of the Cannulated Screw Measuring Device through the protection sleeve to the bone. The reading indicates appropriate screw length, that will **place the screw at the tip of the guide wire.**

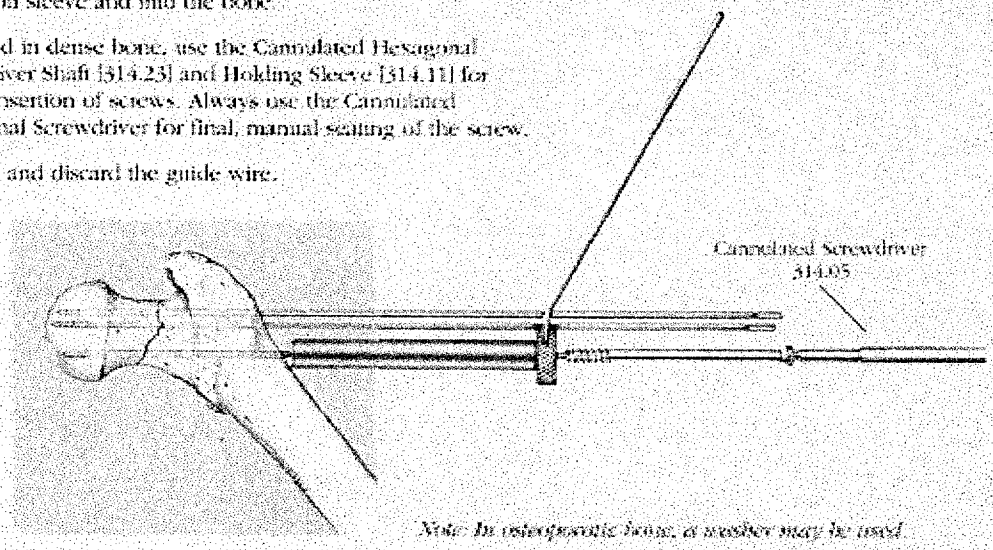


4 Inserting the Screw

Using the Cannulated Hexagonal Screwdriver, place the appropriate length screw over the guide wire, through the protection sleeve and into the bone.

If needed in dense bone, use the Cannulated Hexagonal Screwdriver Shaft [314.23] and Holding Sleeve [314.11] for power insertion of screws. Always use the Cannulated Hexagonal Screwdriver for final, manual seating of the screw.

Remove and discard the guide wire.



Note: In osteoporotic bone, a washer may be used.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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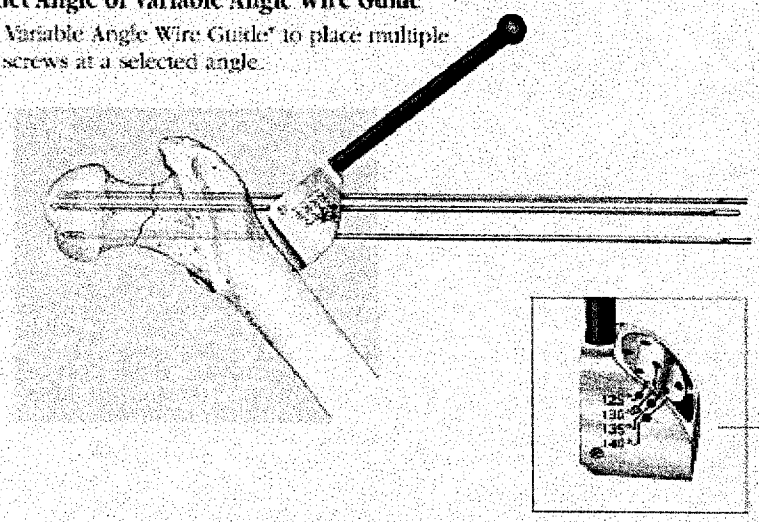
Open Technique–an alternative

1 Set Angle of Variable Angle Wire Guide

Use the Variable Angle Wire Guide* to place multiple parallel screws at a selected angle.



Variable Angle Wire Guide 312.07

2 Insert Guide Wires and Screws

Select a hole pattern and insert the 2.8 mm guide wires through the preselected holes. Once all wires are placed, use the protection sleeve to protect the soft tissue while measuring for and inserting screws.

Note: The Variable Angle Wire Guide will allow placement of washers when wires are placed through nonadjacent holes. Placement through adjacent holes will allow clearance for screws but not for washers.

* Additionally available instrument

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Implant Compatibility

Stainless steel 7.3 mm Cannulated Screws can be used through the following SYNTHES stainless steel implants:

- T-Buttress Plates [240.34–36, 307–309]
- T-Plates [240.13–18]
- L-Buttress Plates [240.44, 54, 405–409, 505–509]
- Lateral Tibial Head Buttress Plates [240.46–50, 56–60]
- Condylar Buttress Plates [240.70–75, 92–95]
- Cobra Head Plates [240.90, 91, 98, 99]
- Spoon Plates [240.05, 06]
- Washer, 13.0 mm [219.99]

7.3 mm Titanium Cannulated Screws can be used through the following SYNTHES titanium implants:

- Titanium T-Buttress Plates [440.34–36]
- Titanium T-Plates [440.13–18]
- Titanium L-Buttress Plates [440.44, 54]
- Titanium LC-DCP® Lateral Tibial Head Buttress Plates [440.515–533]
- Titanium LC-DCP® Condylar Buttress Plates [440.547–555, 567–575]
- Titanium Spoon Plates [440.05, 06]
- Titanium Washer, 13.0 mm [419.99]

Cleaning Tip

Cleaning the cannulation in each instrument is imperative for proper function. Instruments should be cleaned intraoperatively with the 2.8 mm Cleaning Stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire. Instruments should be cleaned postoperatively with the stylet and the cleaning brush.

Technique Tip

The self-drilling, self-tapping flutes of the 7.3 mm cannulated screws make predrilling and pretapping unnecessary in most cases. The 5.0 mm Cannulated Drill Bit and Cannulated Tap facilitate screw insertion in dense bone, if needed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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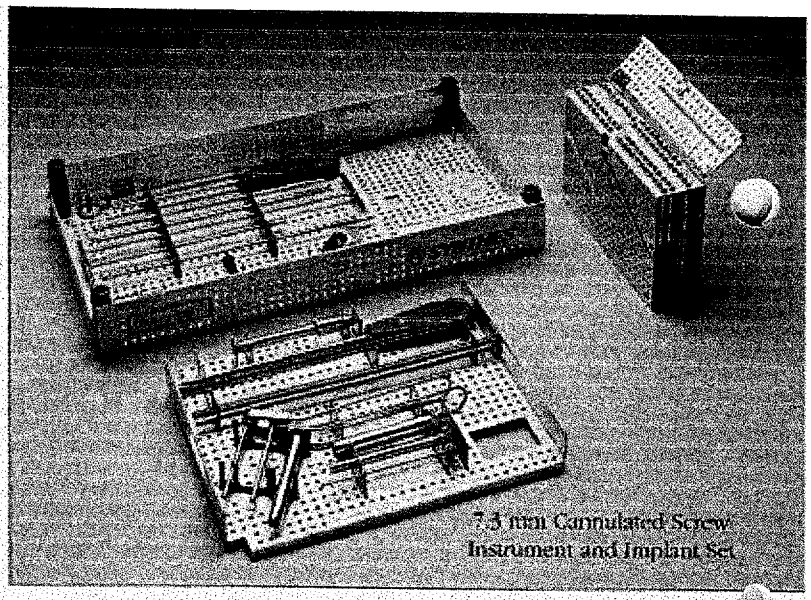
7.3 mm Cannulated Screw Instrument and Implant Set [105.16] and 7.3 mm Titanium Cannulated Screw Instrument and Implant Set [145.16]

Graphic Cases accommodate 7.3 mm cannulated screw instruments and implants and provide organization for inventory control. Upper tray includes instruments for screw insertion. Lower tray provides space for additionally available instruments. Removable screw rack allows separate screw sterilization and may also be ordered separately: [304.294] for stainless steel screws and [304.514] for titanium screws.



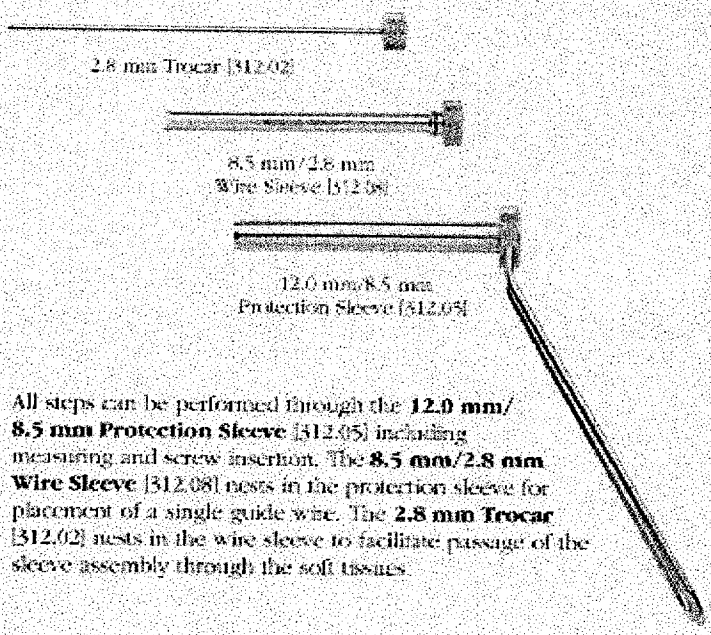
7.3 mm Cannulated Screw Instrument and Implant Set

Instruments

(included in 6.0 set)

2.8 mm Threaded Guide Wire, 300 mm [292.08] maintains reduction during drilling and allows precise placement of the screw in the bone. 10 per set, packaged individually.

Percutaneous Sleeve Assembly:



All steps can be performed through the **12.0 mm/ 8.5 mm Protection Sleeve** [312.05] including measuring and screw insertion. The **8.5 mm/2.8 mm Wire Sleeve** [312.08] nests in the protection sleeve for placement of a single guide wire. The **2.8 mm Trocar** [312.02] nests in the wire sleeve to facilitate passage of the sleeve assembly through the soft tissues.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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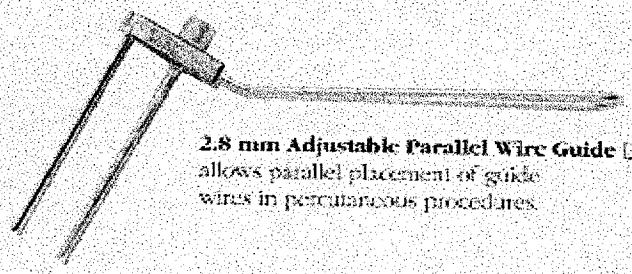
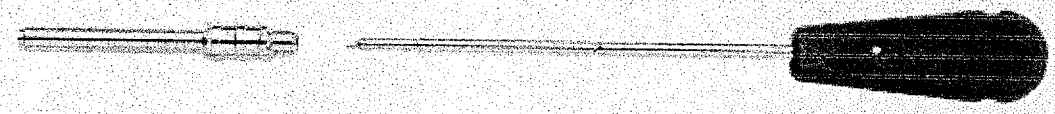
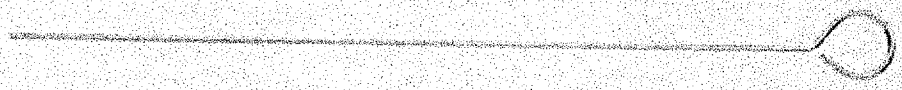


2.8 mm Adjustable Parallel Wire Guide [312.01] allows parallel placement of guide wires in percutaneous procedures.

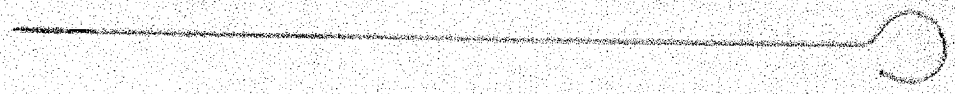
Cannulated Screw Measuring Device [319.70] provides a direct reading of screw length.



Cannulated Hexagonal Screwdriver [314.05] is fully cannulated for insertion of any SYNTHES 7.3 mm Cannulated Screw over the guide wire. Accommodates **Holding Sleeve** [314.11]. *(4.0 mm hex)*

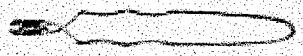


2.8 mm Cleaning Stylet [319.46], for intraoperative cleaning of cannulated instruments.



Note: Clear instrument cannulations intra-operatively with the cleaning stylet. Clean instruments postoperatively with the stylet and the cleaning brush.

2.9 mm Cleaning Brush [319.24], for postoperative cleaning of cannulated instruments.



Screw Forceps [319.97]

5.0 mm Cannulated Drill Bit [310.63], 300 mm/250 mm*, 2.9 mm cannulation for use in dense bone.

*Total length/Effective length

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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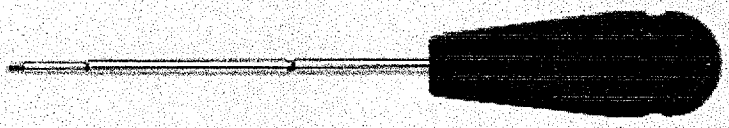
Instruments (cont'd)



Solid Hexagonal Screwdriver [513.93], used for removal of 7.3 mm Cannulated Screws. *(4.0 mm bit)*

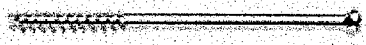
Large Quick Coupling, for Small Air Drill [358.40], for use with 5.0 mm Cannulated Drill Bits and hexagonal screwdriver shafts.

Implants

7.3 mm Cannulated Screw Set [105.16] *(316L stainless steel)*

7.3 mm Cannulated Screws 16 mm thread length:

208.830–875 30–75 mm†, 2 ea.
208.880–890 80–90 mm†, 4 ea.
208.895–910 95–110 mm†, 2 ea.
208.915–930 115–130 mm†, 1 ea.



7.3 mm Cannulated Screws 32 mm thread length:

209.850–890 50–90 mm†, 2 ea.
209.895–930 95–130 mm†, 1 ea.

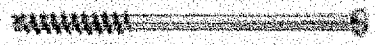
Washer, 13.0 mm [219.99], to prevent screw head from sinking into osteoporotic bone, 6 ea.

† 5 mm increments

7.3 mm Titanium Cannulated Screw Set [145.16] *(titanium)*

7.3 mm Titanium Cannulated Screws 16 mm thread length:

408.830–875 30–75 mm†, 2 ea.
408.880–890 80–90 mm†, 4 ea.
408.895–910 95–110 mm†, 2 ea.
408.915–930 115–130 mm†, 1 ea.



7.3 mm Titanium Cannulated Screws 32 mm thread length:

409.850–890 50–90 mm†, 2 ea.
409.895–930 95–130 mm†, 1 ea.

Titanium Washer, 13.0 mm [439.99], to prevent screw head from sinking into osteoporotic bone, 6 ea.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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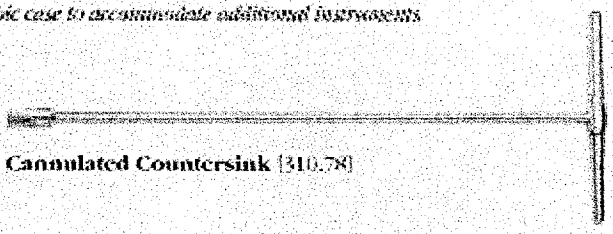
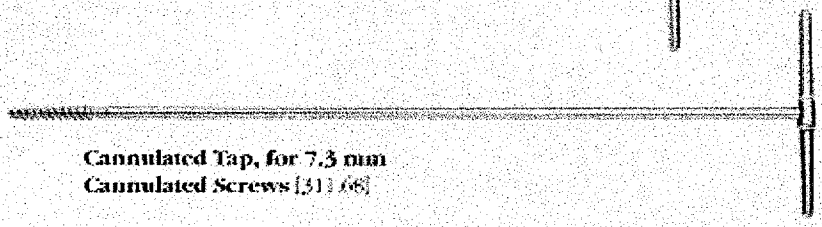
Additionally Available Instruments

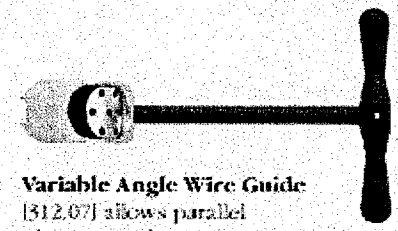
Note: Spaces are provided in the graphic case to accommodate additional instruments.



Cannulated Countersink [310.78]



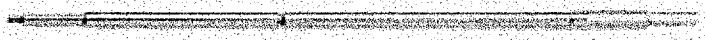
Cannulated Tap, for 7.3 mm Cannulated Screws [311.66]



Variable Angle Wire Guide [312.07] allows parallel placement of guide wires in open procedures.

15.5 mm/15.0 mm Washer Sleeve [312.09] protects soft tissues during placement of screw with washer.

Cannulated Hexagonal Screwdriver Shaft [314.23], for power insertion of 7.3 mm Cannulated Screws. *(4.0 mm hex)*



Solid Hexagonal Screwdriver Shaft [314.04] facilitates removal of 7.3 mm Cannulated Screws. *(4.0 mm hex)*

ComPact Air Drive [511.70]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Set Contents

7.3 mm Cannulated Screw Instrument and Implant Set [105.16] *(stainless steel implants)*

304.299	7.3 mm Cannulated Screw Instrument and Implant Set Graphic Case
208.830–875	7.3 mm Cannulated Screws, 16 mm thread, 30–75 mm†, 2 ea.
208.880–890	7.3 mm Cannulated Screws, 16 mm thread, 80–90 mm†, 4 ea.
208.895–910	7.3 mm Cannulated Screws, 16 mm thread, 95–110 mm†, 2 ea.
208.915–930	7.3 mm Cannulated Screws, 16 mm thread, 115–130 mm†, 1 ea.
209.850–890	7.3 mm Cannulated Screws, 32 mm thread, 50–90 mm†, 2 ea.
209.895–930	7.3 mm Cannulated Screws, 32 mm thread, 95–130 mm†, 1 ea.
219.99	Washer, 13.0 mm, 6 ea.
292.68	2.8 mm Threaded Guide Wire, 300 mm, 10 ea.
310.63	5.0 mm Cannulated Drill Bit, 300 mm/250 mm*, 2.9 mm cannulation, quick coupling
312.01	2.8 mm Adjustable Parallel Wire Guide
312.02	2.8 mm Trocar
312.05	12.0 mm/8.5 mm Protection Sleeve
312.08	8.5 mm/2.8 mm Wire Sleeve
313.93	Solid Hexagonal Screwdriver *(for screw removal; 4.0 mm bit)*
314.05	Cannulated Hexagonal Screwdriver *(4.0 mm bit)*
314.11	Holding Sleeve
319.24	2.9 mm Cleaning Brush
319.46	2.8 mm Cleaning Stylet
319.70	Cannulated Screw Measuring Device
319.97	Screw Forceps
338.49	Large Quick Coupling, for Small Air Drill

7.3 mm Titanium Cannulated Screw Instrument and Implant Set [145.16]

304.540	7.3 mm Titanium Cannulated Screw Instrument and Implant Set Graphic Case
408.830–875	7.3 mm Titanium Cannulated Screws, 16 mm thread, 30–75 mm†, 2 ea.
408.880–890	7.3 mm Titanium Cannulated Screws, 16 mm thread, 80–90 mm†, 4 ea.
408.895–910	7.3 mm Titanium Cannulated Screws, 16 mm thread, 95–110 mm†, 2 ea.
408.915–930	7.3 mm Titanium Cannulated Screws, 16 mm thread, 115–130 mm†, 1 ea.
409.850–890	7.3 mm Titanium Cannulated Screws, 32 mm thread, 50–90 mm†, 2 ea.
409.895–930	7.3 mm Titanium Cannulated Screws, 32 mm thread, 95–130 mm†, 1 ea.
419.99	Titanium Washer, 13.0 mm, 6 ea.
292.68	2.8 mm Threaded Guide Wire, 300 mm, 10 ea.
310.63	5.0 mm Cannulated Drill Bit, 300 mm/250 mm*, 2.9 mm cannulation, quick coupling
312.01	2.8 mm Adjustable Parallel Wire Guide
312.02	2.8 mm Trocar
312.05	12.0 mm/8.5 mm Protection Sleeve
312.08	8.5 mm/2.8 mm Wire Sleeve
313.93	Solid Hexagonal Screwdriver *(for screw removal; 4.0 mm bit)*
314.05	Cannulated Hexagonal Screwdriver *(4.0 mm bit)*
314.11	Holding Sleeve
319.24	2.9 mm Cleaning Brush
319.46	2.8 mm Cleaning Stylet
319.70	Cannulated Screw Measuring Device
319.97	Screw Forceps
338.49	Large Quick Coupling, for Small Air Drill

Additionally Available

7.3 mm Cannulated Screws *(stainless steel)*

208.935–950	16 mm thread, 135–150 mm†
209.620–730	fully threaded, 20–130 mm†
209.845, 935–950	32 mm thread, 45 mm and 135–150 mm†

7.3 mm Titanium Cannulated Screws

408.935–950	16 mm thread, 135–150 mm†
409.620–730	fully threaded, 20–130 mm†
409.845, 935–950	32 mm thread, 45 mm and 135–150 mm†

Instruments

310.78	Cannulated Countersink
311.68	Cannulated Tap, for 7.3 mm Cannulated Screws
312.07	Variable Angle Wire Guide
312.09	15.5 mm/13.0 mm Washer Sleeve
314.04	Solid Hexagonal Screwdriver Shaft *(for screw removal; 4.0 mm bit)*
314.23	Cannulated Hexagonal Screwdriver Shaft *(4.0 mm bit)*
311.70	OrthoPact Air Drive

† 5 mm increments
* Total length/Effective length

SYNTHES (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301-0800
Telephone: 610-647-9700
Fax: 610-251-9056
To order: 1-800-523-0322

SYNTHES (CANADA) LTD.
111 Drumlin Road
Suite 110
Mississauga, Ontario L4Z 1X3
Telephone: 905-568-1711
Fax: 905-568-1662
To order: 1-800-668-1119

SYNTHES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DuVal® Cannulated Screws

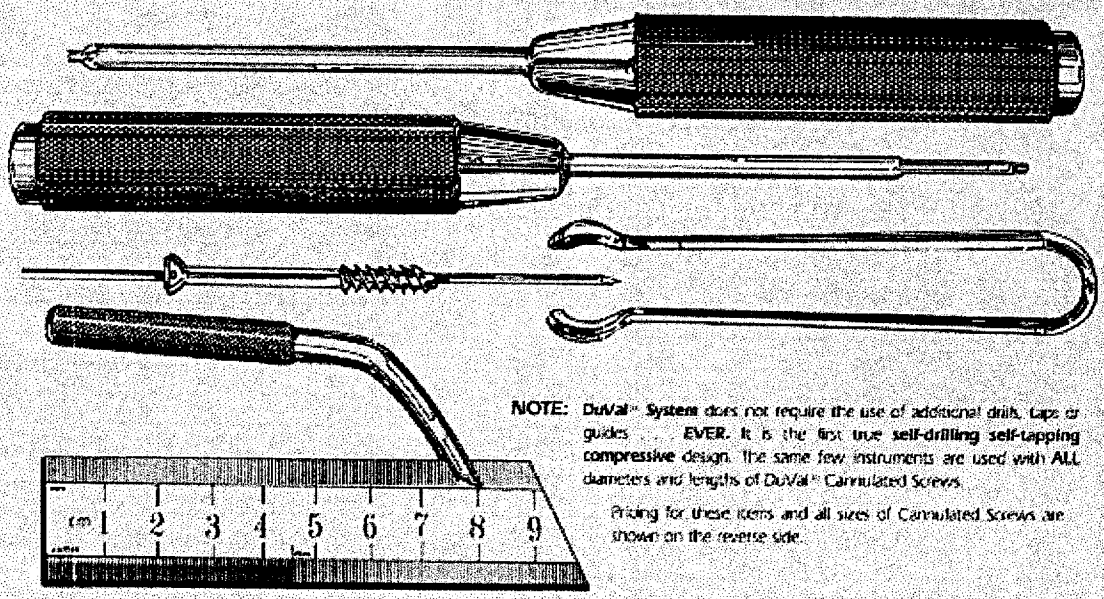
Introduction

The DuVal® Cannulated Screw System is designed to produce compressive forces in fractures or osteotomies, in both diaphyseal and metaphyseal bone. The wide range of thread diameters and lengths allow usage under the most difficult circumstances. *Purchase and compression are achieved in any type bone.*

Temporary stabilization is achieved through the use of a *common .045" K-Wire* that doubles as a guide wire. Permanent fixation is achieved with the **self-drilling, self-tapping, compressive** DuVal® Screw that *eliminates* overdrilling, tapping and complicated guides, sleeves or gauges.

- Variable threads guarantee proper screw purchase in the distal fragment.
- Triple cutting tips* ensure ease of penetration into any density of bone.
- Simple instrumentation offers assurance of uncomplicated procedures.
- DuVal® systems do not include supplemental drills, taps, special guide pins or complicated gauges. None are needed - none are offered.
- Each screw is prepacked with a precision cut guide wire.

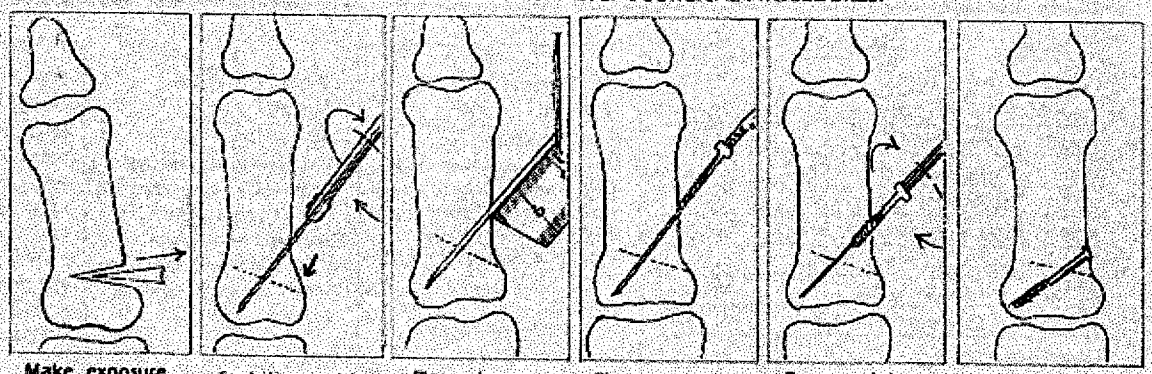
DuVal® Instrumentation for Cannulated Screws



NOTE: DuVal® **System** does not require the use of additional drills, taps or guides . . . **EVER.** It is the first true **self-drilling self-tapping compressive** design. The same few instruments are used with **ALL** diameters and lengths of DuVal® Cannulated Screws.

Pricing for these items and all sizes of Cannulated Screws are shown on the reverse side.

DRAWINGS DO NOT REPRESENT ACTUAL SURGICAL PROCEDURES.



Make exposure of fracture or osteotomy site.

Stabilize with guide wire, position countersink on guide wire, press against bone rotating clockwise, 6-10 times.

Place ruler gauge on guide wire to determine depth of penetration into bone. Read screw length from ruler, then remove ruler.

Place screw on guide wire, followed by screw driver, fitting drive onto screw head.

Turn driver clockwise to drive screw into bone-screw will eliminate lateral stress risers, & tap threads into the bone hole.

Screw cuts forward and reverse making it easily removable, after healing, if desired.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DuVal® Sizing & Pricing:

Prices are for a package of one screw

2.2mm Cannulated Cortical Lag Screws

Catalog	Description	Titanium Stainless	Medipure Titanium*
P222-08	8mm long, 2.8mm Thread	$54.50	$98.50
P222-10	10mm long, 3.5mm Thread	$54.50	$98.50
P222-12	12mm long, 4.2mm Thread	$54.50	$98.50
P222-14	14mm long, 4.9mm Thread	$54.50	$98.50
P222-16	16mm long, 5.6mm Thread	$54.50	$98.50
P222-18	18mm long, 6.3mm Thread	$54.50	$98.50
P222-20	20mm long, 7.0mm Thread	$54.50	$98.50
P222-22	22mm long, 7.7mm Thread	$54.50	$98.50
P222-24	24mm long, 8.4mm Thread	$54.50	$98.50
P222-26	26mm long, 9.1mm Thread	$54.50	$98.50
P222-28	28mm long, 9.8mm Thread	$54.50	$98.50
P222-30	30mm long, 10.5mm Thread	$54.50	$98.50

3.5mm Cannulated Combination Lag Screws

Catalog	Description	Titanium Stainless	Medipure Titanium*
P235-10	10mm long, 4.0mm Thread	$49.50	$98.50
P235-12	12mm long, 4.9mm Thread	$49.50	$98.50
P235-14	14mm long, 5.8mm Thread	$49.50	$98.50
P235-16	16mm long, 6.7mm Thread	$49.50	$98.50
P235-18	18mm long, 7.6mm Thread	$49.50	$98.50
P235-20	20mm long, 8.5mm Thread	$49.50	$98.50
P235-22	22mm long, 9.4mm Thread	$49.50	$98.50
P235-24	24mm long, 10.3mm Thread	$49.50	$98.50
P235-26	26mm long, 11.2mm Thread	$49.50	$98.50
P235-28	28mm long, 12.1mm Thread	$49.50	$98.50
P235-30	30mm long, 13.0mm Thread	$49.50	$98.50
P235-32	32mm long, 13.9mm Thread	$54.50	$98.50
P235-34	34mm long, 14.8mm Thread	$54.50	$98.50
P235-36	36mm long, 15.7mm Thread	$54.50	$98.50
P235-38	38mm long, 16.6mm Thread	$54.50	$98.50
P235-40	40mm long, 17.5mm Thread	$54.50	$98.50
P235-42	42mm long, 18.4mm Thread	$54.50	$98.50
P235-44	44mm long, 19.3mm Thread	$54.50	$98.50
P235-46	46mm long, 20.2mm Thread	$54.50	$98.50
P235-48	48mm long, 21.1mm Thread	$54.50	$98.50
P235-50	50mm long, 22.0mm Thread	$54.50	$98.50

2.7mm Cannulated Combination Lag Screws

Catalog	Description	Titanium Stainless*	Medipure Titanium*
P227-08	8mm long, 2.8mm Thread	$49.50	$98.50
P227-10	10mm long, 3.5mm Thread	$49.50	$98.50
P227-12	12mm long, 4.2mm Thread	$49.50	$98.50
P227-14	14mm long, 4.9mm Thread	$49.50	$98.50
P227-16	16mm long, 5.6mm Thread	$49.50	$98.50
P227-18	18mm long, 6.3mm Thread	$49.50	$98.50
P227-20	20mm long, 7.0mm Thread	$49.50	$98.50
P227-22	22mm long, 7.7mm Thread	$49.50	$98.50
P227-24	24mm long, 8.4mm Thread	$49.50	$98.50
P227-26	26mm long, 9.1mm Thread	$49.50	$98.50
P227-28	28mm long, 9.8mm Thread	$49.50	$98.50
P227-30	30mm long, 10.5mm Thread	$49.50	$98.50
P227-32	32mm long, 11.2mm Thread	$54.50	$98.50
P227-34	34mm long, 11.9mm Thread	$54.50	$98.50
P227-36	36mm long, 12.6mm Thread	$54.50	$98.50
P227-38	38mm long, 13.3mm Thread	$54.50	$98.50
P227-40	40mm long, 14.0mm Thread	$54.50	$98.50

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Catalog	Description	Titanium Stainless*	Medipure Titanium*
P242-10	10mm long, 4.0mm Thread	$54.50	$98.50
P242-12	12mm long, 4.9mm Thread	$54.50	$98.50
P242-14	14mm long, 5.8mm Thread	$54.50	$98.50
P242-16	16mm long, 6.7mm Thread	$54.50	$98.50
P242-18	18mm long, 7.6mm Thread	$54.50	$98.50
P242-20	20mm long, 8.5mm Thread	$54.50	$98.50
P242-22	22mm long, 9.4mm Thread	$54.50	$98.50
P242-24	24mm long, 10.3mm Thread	$54.50	$98.50
P242-26	26mm long, 11.2mm Thread	$54.50	$98.50
P242-28	28mm long, 12.3mm Thread	$54.50	$98.50
P242-30	30mm long, 13.0mm Thread	$54.50	$98.50
P242-32	32mm long, 13.9mm Thread	$59.50	$98.50
P242-34	34mm long, 14.8mm Thread	$59.50	$98.50
P242-36	36mm long, 15.7mm Thread	$59.50	$98.50
P242-38	38mm long, 16.6mm Thread	$59.50	$98.50
P242-40	40mm long, 17.5mm Thread	$59.50	$98.50
P242-45	45mm long, 19.8mm Thread	$59.50	$98.50
P242-50	50mm long, 22.0mm Thread	$59.50	$98.50
P242-55	55mm long, 24.3mm Thread	$59.50	$98.50
P242-60	60mm long, 26.5mm Thread	$59.50	$98.50

Catalog	Description	Price
P202C	Cannulated 2.5mm Driver	$155.00
P310-86*	Cannulated Driver/Countersink	$255.00
P310-86A	Cannulated Countersink	$155.00
P206	Depth Gauge Ruler, 100mm	$28.50
P205*	Screw Holding Forceps	$32.80
P204*	Washer for Osteoporotic Bone	$6.00
G68345	DuVal Guide Pin, 100mm	$3.00
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*Optional Items

P200BC Akin-Austin
$395.00
$491.00 Value
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G68345 Inplace Guide Wires (x2)
P202C Cannulated Driver
P206 Guide Depth Gauge
P310-86 Cannulated Countersink

P200 DC Office Set
$895.00
$1088.50 Value
P2 — Cannulated Screws (x6)
G68345 Inplace Guide Wires (x6)
P202C Cannulated Driver
P206 Guide Depth Gauge
P310-86 Cannulated Countersink
P201-S/B Autoclave Screw Tray

P200 HC Hospital Set
$2495.00
$2703.50 Value
P227 — Cannulated Screws (x12)
P235— Cannulated Screws (x12)
P202C Cannulated Driver (x2)
P206 Guide Depth Gauge
P310-86 Cannulated Countersink (x2)
P201S/B Autoclave Screw Tray
P201 Autoclave Container
G68345 Guide Wires (x24)

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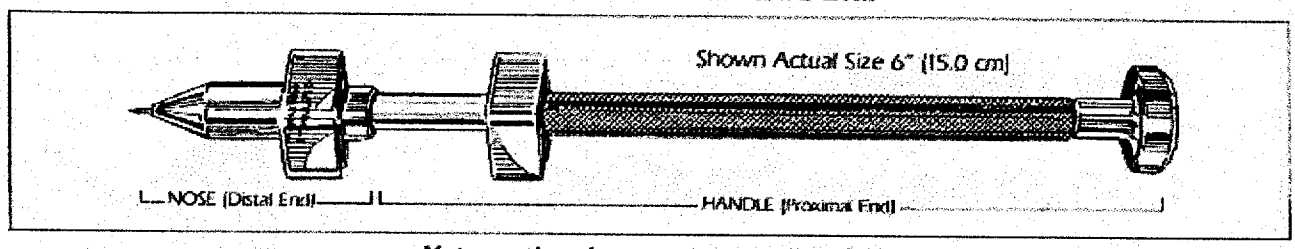

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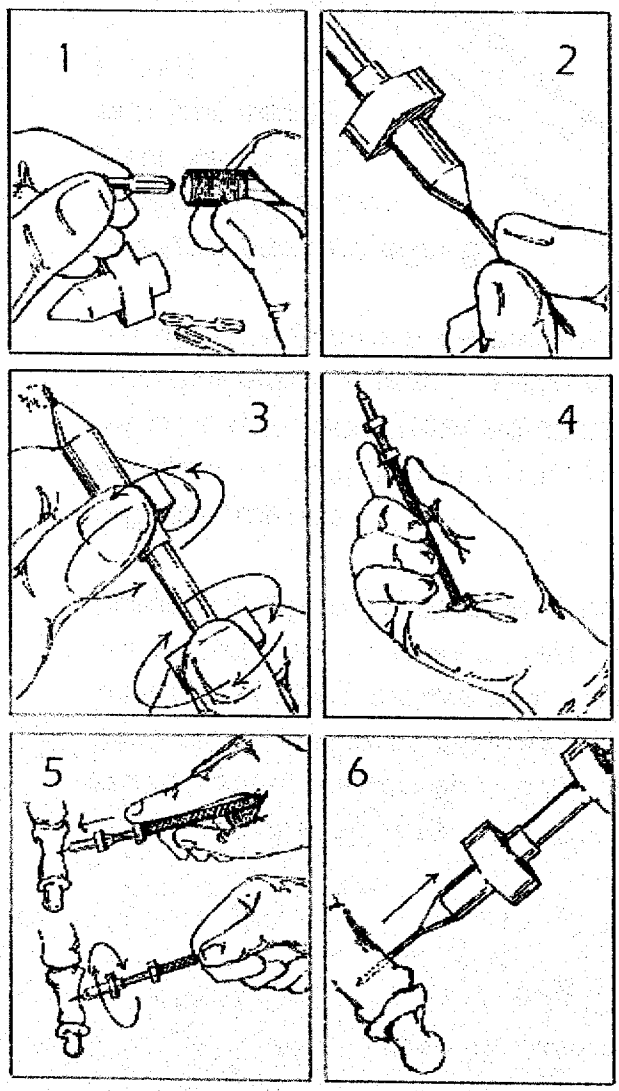

Instructions for using the Scott Wire Drill System:

1) Remove distal end (nose) of the drill by unscrewing it from the handle.
Insert the desired collet into handle (as shown). Replace the distal end to the handle and tighten slightly.

2) Insert the corresponding Kirshner wire into the distal end of the unit (as shown).

3) Once the Kirshner wire is in place (1/4" extended from nose), continue tightening until the collet clamps down on the Kirshner wire. May require light pressure.

4) Place the proximal end of the unit into the center of your palm (as shown) and allow your fingers to close down around the remaining handle.

5) To create the drilling motion, place the Kirshner wire tip (1/4" exposed) to the bone surface. Apply pressure with your palm and turn the drill with your fingers in a clockwise motion until proper fixation is achieved (as shown).

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APPENDIX C

Osteo AG Authorization Letter

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OSTEO AG

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Swiss Bank Corporation, Solothurn

Food and Drug Administration
Center for Devices and
Rehabilitative Health
P.O. Box 3002
Rockville, Maryland
20847-3002
USA

- 5 1997

Your reference | Our reference 6914/SH/is | Selzach February 28, 1997

U.S. Designated Agent (USDA)

Dear Sirs

OSTEO AG, a manufacturer of orthopeadic implants located in Selzach, Switzerland, does hereby designate Osteonics Corporation as its U.S. Designated Agent. The Establishment Registration number for Osteonics Corp. is 2243265 and their address is as follows:

Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

As its Designated Agent, Osteonics shall act on behalf of OSTEO AG as its Official Correspondent, submit Medical Device Reports (MDRs) and maintain associated files and procedures, as well as be responsible for OSTEO AG's registration, device listing and premarket notification submission to FDA.

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CH-2545 SELZACH (SWITZERLAND)

OSTEO AG

Thank you for your attention to this matter.

Regards,

O S T E O A G

T. Wahl
Technical Director

S. Hasler
Project Manger/
Regulatory Affairs

cc: R. Koch - Osteonics
B. Staub- Osteonics

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APPENDIX D

Chapters 7 and 15 from Cannulated Screw Fixation: Principles and Operative Techniques

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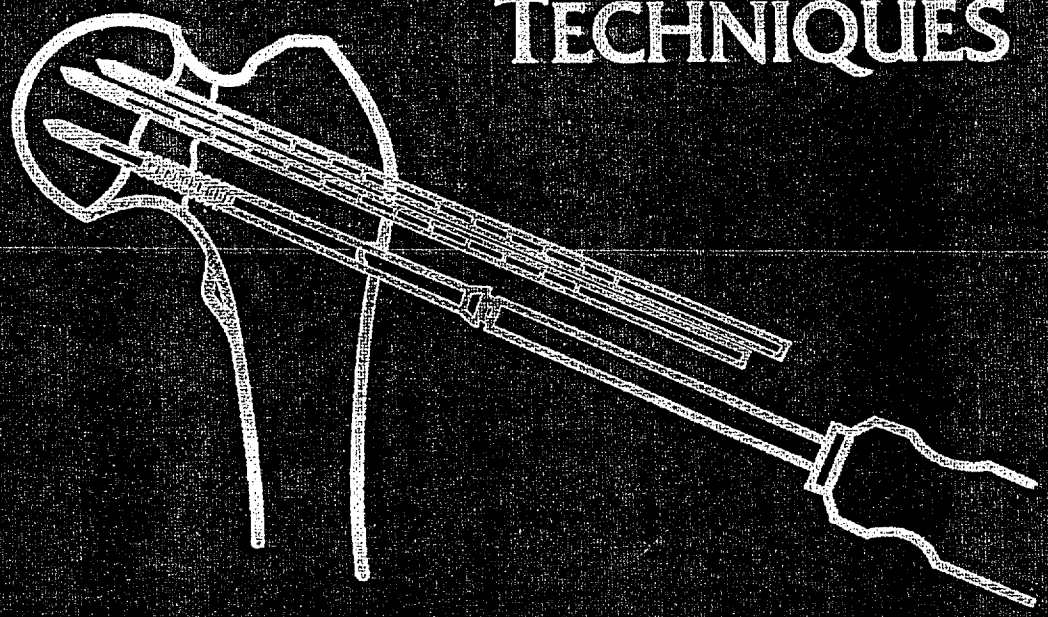
Cannulated Screw Fixation

Principles and Operative Techniques



Stanley E. Asnis
Richard F. Kyle
Editors

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Stanley E. Asnis, M.D. Richard F. Kyle, M.D.
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7

Pelvic and Acetabular Fractures

Dana C. Mears

Significant or displaced fractures of the pelvic ring and acetabulum constitute a diverse group of skeletal injuries that usually result from motor vehicular accidents, industrial trauma, or falls from great heights. The typical pelvic ring disruption requires the application of immense forces to the patient, who thereby is likely to present with other serious or life-threatening injuries involving the musculoskeletal (85%), respiratory (60%), central nervous (40%), gastrointestinal (30%), urologic (12%), and cardiovascular (6%) systems.[1] The management of a pelvic ring fracture, therefore, requires a concomitant diagnosis and treatment of the other systemic and musculoskeletal injuries. About 50% of acetabular fracture patients have sustained associated injuries, and about 30% have experienced injuries to three or more organ systems. As McMurtry et al.,[2] Tile,[3] and others[4] have emphasized, a meticulous diagnostic protocol is needed that prioritizes the evaluation of diverse organ systems by the degree of urgency. From a recent report by Dalal et al.,[5] a correlation of the pelvic injury pattern with the statistical likelihood for particular patterns of associated visceral injuries may facilitate the application of diverse diagnostic procedures.

Historically, the stabilization of the pelvic ring was deemed to be of secondary importance after the preliminary resuscitative phase of management had been completed. In the patient who is hemodynamically unstable, acute stabilization of the pelvic ring provisionally by resort to a pneumatic anti-shock garment, and more definitively by an external frame or comparable pelvic clamp, assists in the provision of hemostasis.[1,6] Such a method can facilitate the elimination of enforced recumbency with the associated predilection for thromboembolic problems, decubitus ulcers, urinary retention, urinary tract infections, and atelectasis. External fixation is biomechanically inadequate to effectively immobilize many injury patterns, especially those with a major disruption or bilateral disruption of the posterior pelvic ring or associated acetabular fractures.[7] In common with other intraarticular disruptions, an acetabular fracture is exceedingly vulnerable to progress to posttraumatic arthritis unless an accurate reduction is achieved. During the past 20 years, extensive clinical and biomechanical research has focused upon attempts to devise operative approaches, reduction strategies, and fixation methods that are appropriate for a broad spectrum of pelvic and acetabular fractures.[8] The application of cannulated screws has become an attractive form of fixation that is applicable for certain injury patterns. The assets include a minimally invasive insertional mode combined with radiographic targeting of a preliminary guide wire. Lag screw fixation is a particularly impressive form of stabilization for the ring-like pelvis, where bending movements are relatively low and frictional properties of interdigitating fracture fragments are outstanding.[9]

As a supplementary clinical problem and one of ever-increasing presentation, insufficiency fractures of the elderly are complicated by the pathologically osteoporotic bone.[10] Historically, these problems were managed by primary care physicians and rheumatologists who were under the mistaken hypothesis that conservative methods were uniformly successful. Currently, orthopaedists are requested to assist in the management of a small percentage, but ever-increasing number of such patients who expe-

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rience chronic pain and progressive subsidence of their pelvic fractures that follow a trivial fall or other mishap. Usually the fractures are stabilized in situ so that an extensile surgical approach is unnecessary. For an insufficiency fracture, cannulated screw fixation is a particularly attractive form of stabilization.

This chapter focuses on the role of cannulated screws for the fixation of many types of pelvic and acetabular fractures.

Structural Anatomy of the Pelvis

Upon inspection of the front of the pelvis and torso, the most prominent features are the symmetrical iliac crests, anterosuperior iliac spines, and the symphysis pubis. In a lean individual, the inguinal ligament visibly spans from the anterosuperior iliac spine to the ipsilateral pubis tubercle in a cord-like fashion. If the iliac crest is traced posteriorly, the palpating finger courses from the crest to the posterosuperior iliac spine and continues obliquely in a medial and distal direction to the tip of the sacrum and coccyx. Anterior or posterior scrutiny of the torso is notable for the lateral prominence of the greater trochanter and the allied abductor musculature that originates along the iliac crest and adjacent lateral ilium. Upon initial inspection of the patient who has sustained a major disruption of the pelvic ring or an acetabular fracture, a careful scrutiny and palpation of these bony landmarks may indicate an asymmetrical disposition, instability, or other abnormality.

The pelvic girdle is a ring-like structure comprising two innominate bones, which articulate anteriorly in a direct fashion at the symphysis and posteriorly by an interposed sacrum (Figure 7.1). In turn, the sacrum articulates superiorly with the lumbar spine and inferiorly with the coccyx. The pelvic ring is subdivided into an upper or false pelvis, a clinical extension of the abdomen, and an inferior or true pelvis. The dividing line, the pelvic inlet, is an oblique plane that passes through the upper symphysis pubis, and the iliopectineal lines to the sacral promontory. In an erect posture, weight-bearing forces are transmitted from the spinal column through

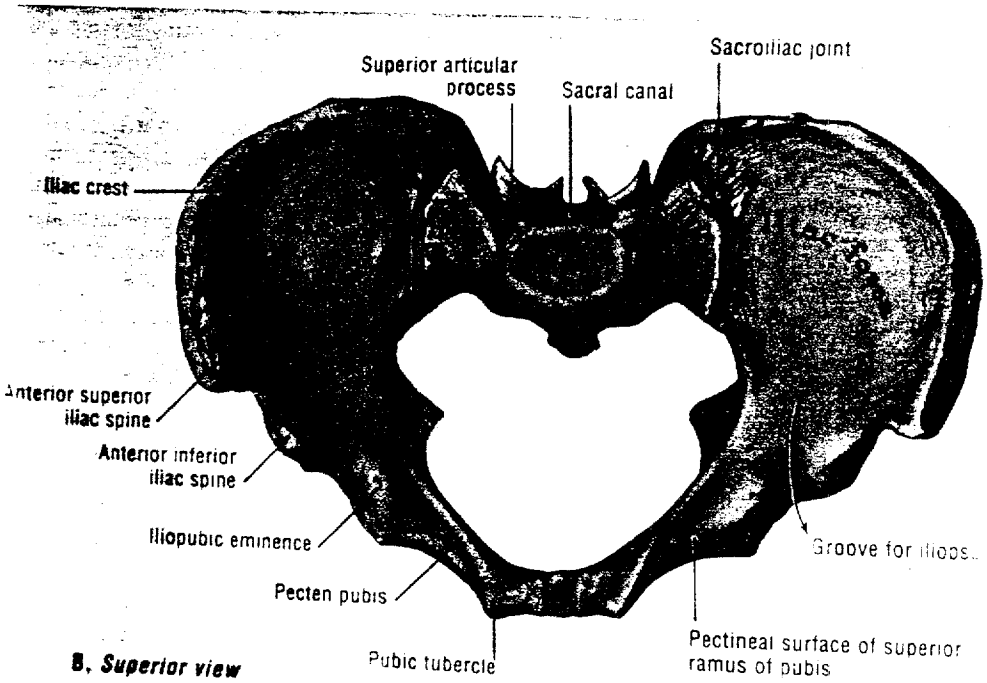

FIGURE 7.1. Bony anatomy of the pelvis. (Reprinted with permission from Agur.[12])

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the sacrum and sacroiliac joints, along the thick sections of ilia, to the acetabulae and, thereby, to the proximal femora. While this femorosacral arch is crucial for weight transmission in an erect posture, in a sitting position weight-bearing forces pass through the sacroiliac joints into the ilia with a progression into the ischial tuberosities via either ischiosacral arch. To a lesser degree, weight-bearing forces are transmitted around the anterior portions of the pelvic ring. With the limited mobility of the pelvic articulations at the sacroiliac and sacrococcygeal joints and the symphysis pubis, the muscles originating on the pelvis provide locomotion for the lower extremities or postural support for the torso. There is no demonstrable motion of the articulations of the pelvic ring itself, apart from that associated with childbirth.

Letournel and Judet[11] redefined the innominate bone as a bony support for the acetabulum. The acetabulum is perceived as a socket contained within two arms of an inverted Y formed by a stout posterior column, the ilioischial component, and a longer anterior column that extends from the anterior extension of the superior iliac crest to the pubic symphysis (Figure 7.2). The internal surface of the acetabulum constitutes the quadrilateral surface on the inner aspect of the body of the ischium. The posterior border of the ilioischial column is formed superiorly by the ilium and inferiorly by the greater and lesser sciatic notches separated by the ischial spine. The iliopubic column is subdivided into iliac, acetabular, and pubic segments. The iliac segment is notable for a lateral pillar or gluteal ridge that extends superiorly from the roof of the acetabulum to the gluteus medius tubercle. Its anterior border possesses two thick projections, the anterior superior and anterior inferior iliac spines separated by the interspinous notch. The acetabular portion continues medially with a thickened segment of anterior wall, the iliopubic eminence, that attaches to the pubic ramus. In fact, the anterior wall is dwarfed by the larger posterior wall, thereby creating the relative acetabular anteflexion of about 20°.

The sacrum is a large, irregular pyramid with five surfaces (Figure 7.3). Its embryological origin is five fused vertebrae of progressively diminishing size from superior to inferior. The principal component, the first sacral vertebra, is tilted forward in the erect posture to an angle of about 30° to 40°. The slightly convex posterior surface possesses a thickened medial crest as a modification of the spinous processes. The slightly concave anterior surface forms the posterior pelvic wall. Matching pairs of sacral foramina are evident on both the anterior and posterior surfaces. A lateral mass of bone, the ala, affords a thickened buttress for the articular portion of either sacroiliac joint with a corresponding iliac buttress. The sacrum is positioned about 3 cm anterior to the posterior superior spines and the adjacent posterior iliac crests. The recessed position of either sacroiliac joint compromises the view realized by a posterior approach and thereby hampers the assessment of accuracy achieved with an open reduction.

The bony pelvis is notable for thickened condensations of bone that provide attractive sites for the application of internal fixation to the innominate bone (Figure 7.4). Screws can be inserted into drill holes prepared in the anterior and posterior iliac spines, the gluteal tubercle, the gluteal ridge, the pubic ramus, and along the iliopubic and ilioischial columns. Screws also can be inserted across the sacroiliac joint and the symphysis pubis. For immobilization of a longitudinal sacral fracture (Figures 7.3d and 7.5), iliosacral screws can extend from the ipsilateral ilium into the first or second sacral body. In the presence of a bilateral sacral fracture, lengthy screws can be used that extend from one ilium and across the sacrum into the other ilium. As an alternative, bilateral iliosacral screws can be used, or as another option, screws can be inserted horizontally that extend from one posterior superior spine to the other with a pathway that is similar to that of a sacral bar and behind the sacral bodies.

Dense ligaments anchor the sacroiliac joints, especially the posterior interosseous ligaments. The corresponding anterior sacroiliac ligaments are relatively attenuated. Two crucial supplementary ligaments afford rotational stability to the hemipelvis. The strong sacrotuberous ligament is a fan-shaped band that extends from the lateral portion of the dorsum of the sacrum and the adjacent iliac spines to the ischial tuberosity. A supplementary sacrospinous ligament is a

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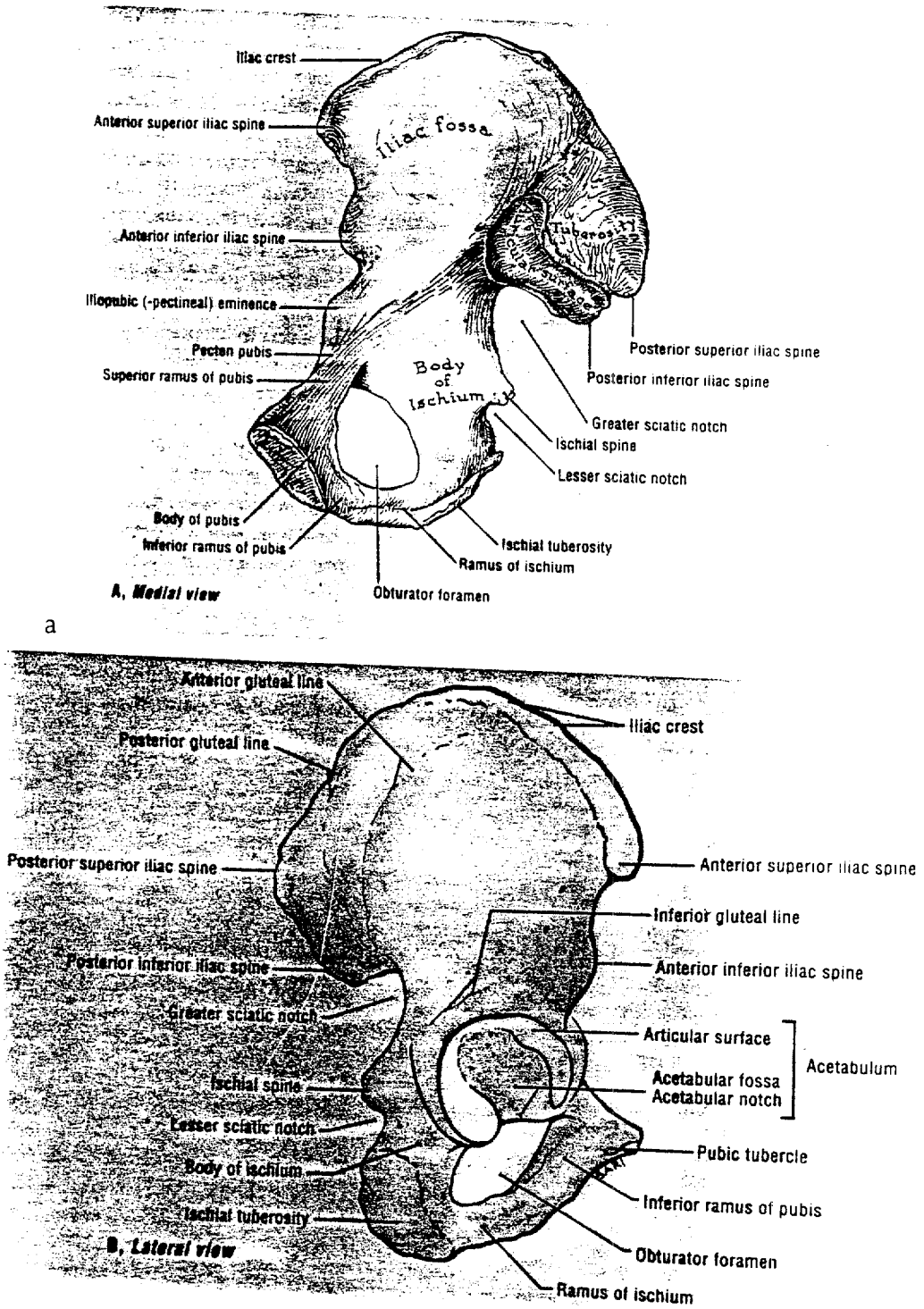

FIGURE 7.2. Bony anatomy of the acetabulum. (a) Medial view. (b) Lateral view. (Reprinted with permission from Agur.[12])

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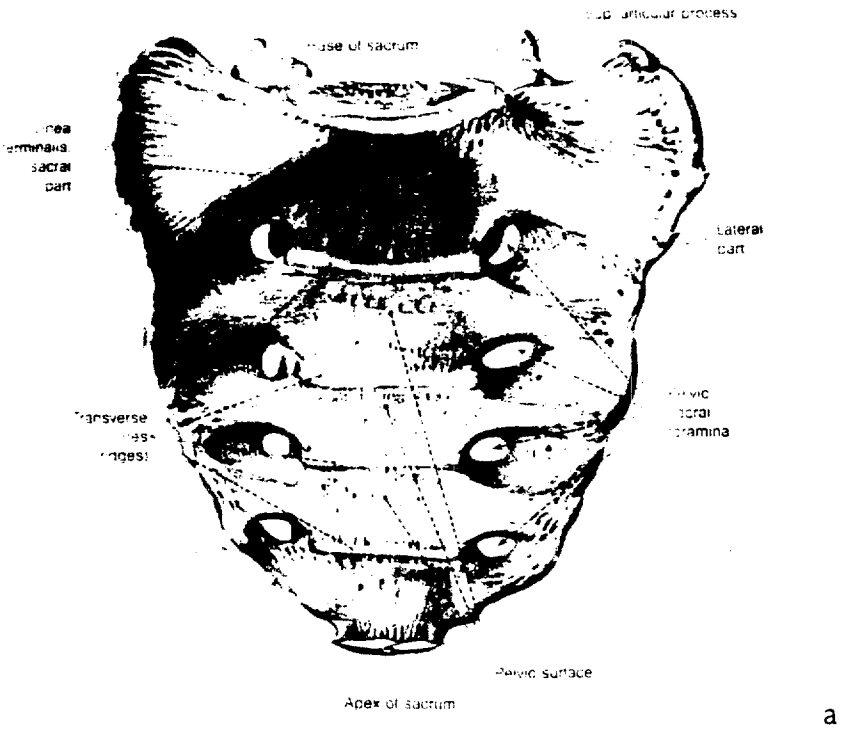

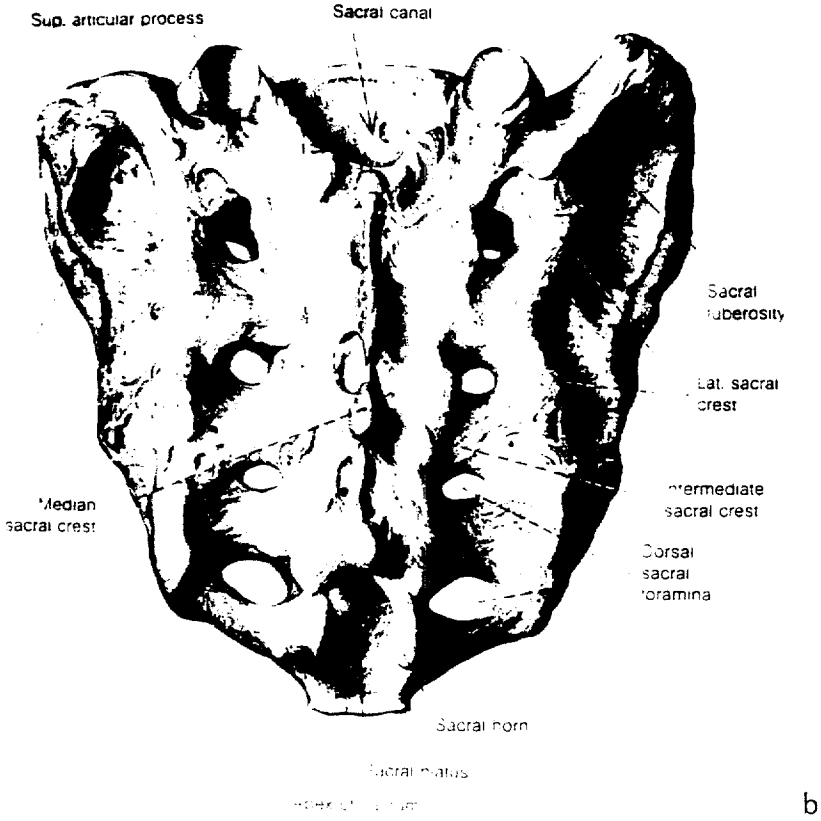

FIGURE 7.3. Bony anatomy of the sacrum. (a) Anterior view. (b) Posterior view.

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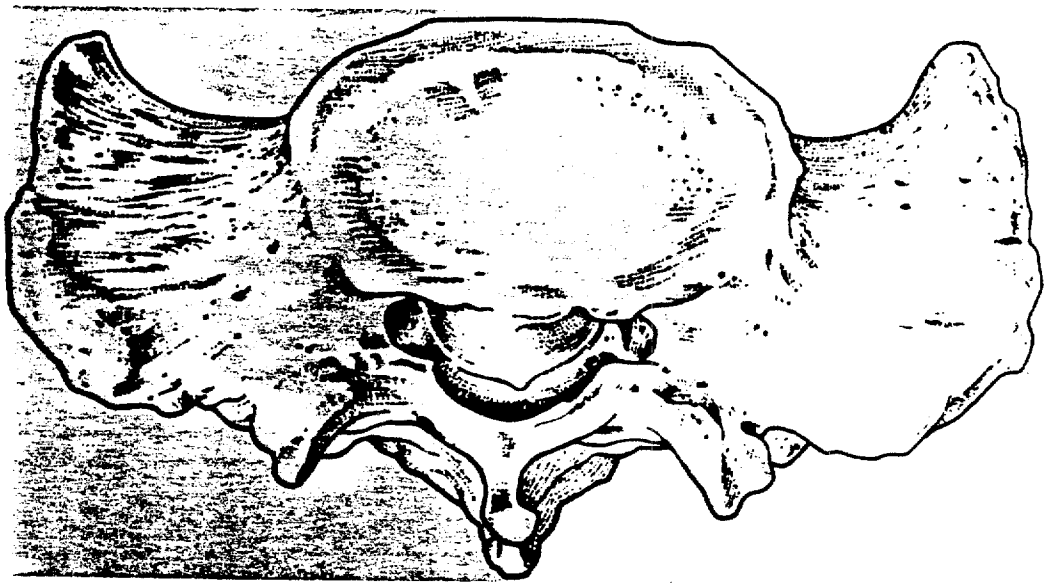

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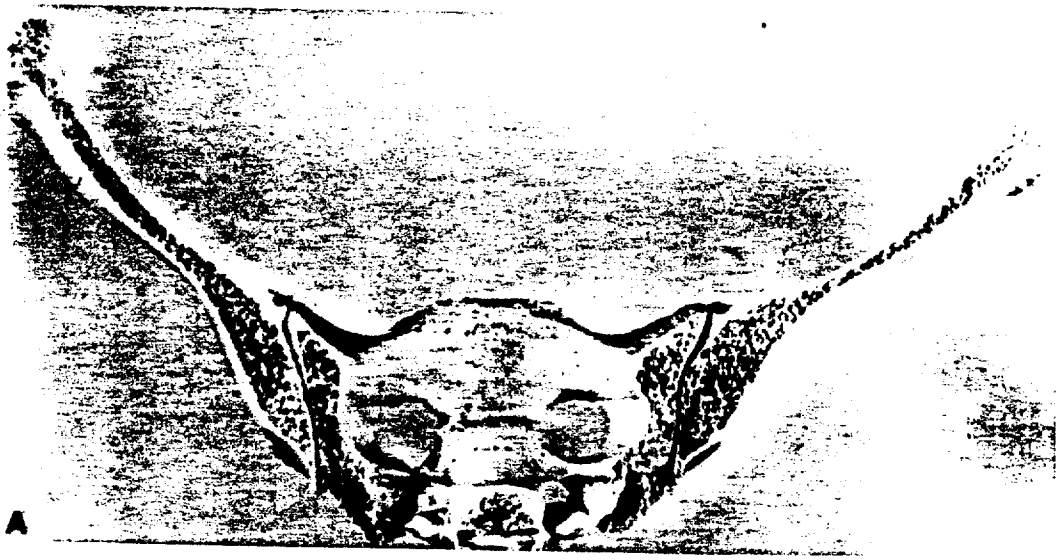

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FIGURE 7.3 (*continued*) (c) Superior view. (d) Transaxial view through S-1 body. (a & b reprinted with permission from Ferner and Staubesand.[49] c & d reprinted with permission from Rockwood and Green.[50])

dense triangular sheet that is deep to the sacrotuberous ligament. It arises from the lateral margin of the sacrum and coccyx and inserts on the ischial spine. The sacrospinous ligament divides the ischial area into the greater sciatic notch and the lesser sciatic foramen. At the lumbosacral articulation, iliolumbar ligaments secure the axial skeleton to the pelvis and thereby supplement the strong intervertebral disk complex. All of the posterior pelvic ligaments constitute a tension band that resists rotational and longitudinal shearing forces. With its wedge-shaped configuration, the sacrum is suspended by the ligaments as a self-locking system.

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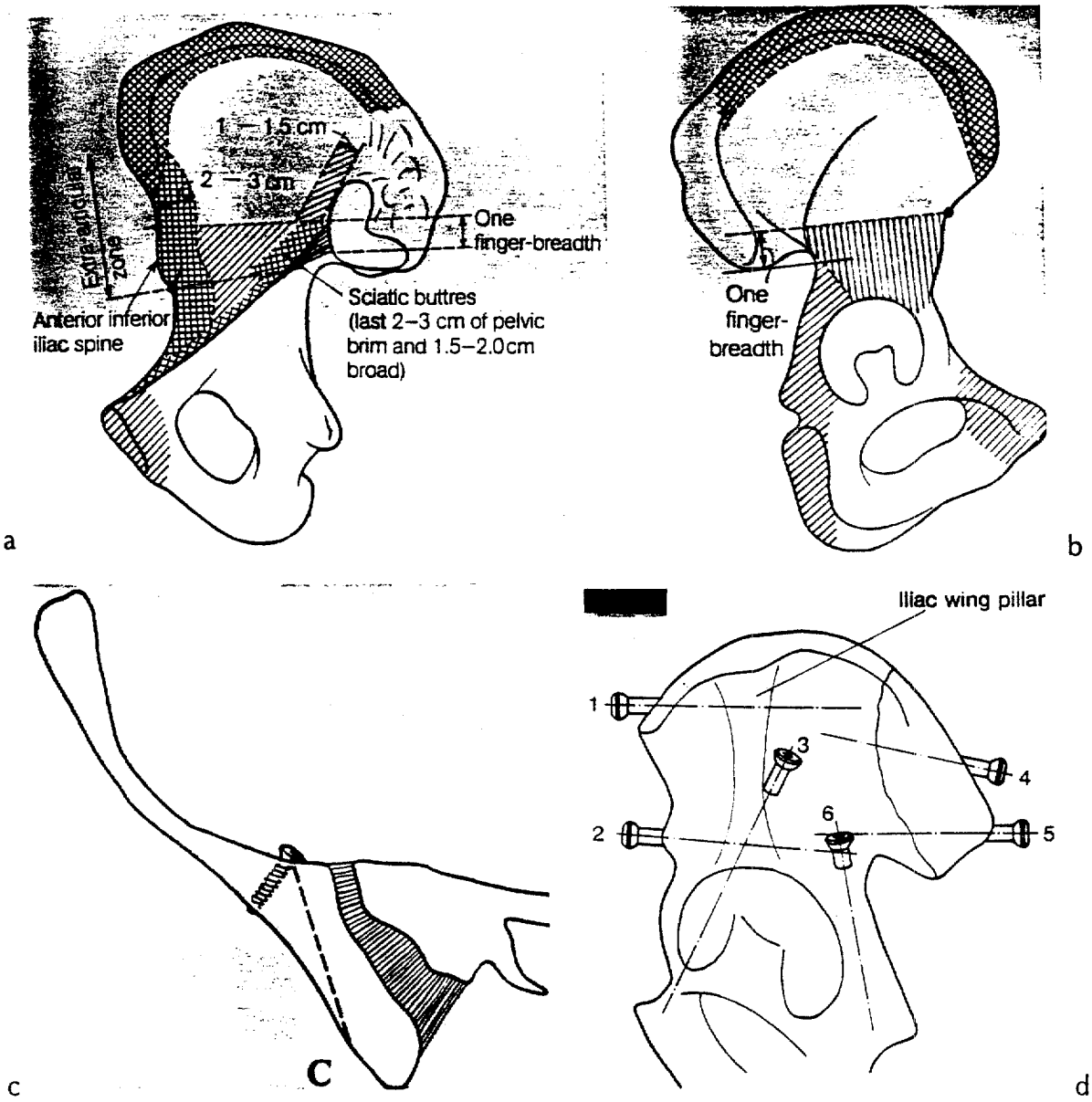

FIGURE 7.4. Pelvic bony condensations as suitable sites for insertion of lag screws. Vertical or oblique striations the thickest zones. Cross-hatched areas correspond to dense areas. (a) Inner view. (b) Outer view. (c) Transectional view. From the same starting point, screws of very different length can be inserted. (d) Standard pathways for lag screw insertion: 1, Anterior iliac crest; 2, Anterior inferior spine to greater sciatic buttress; 3, Anterior column; 4, Posterior iliac crest; 5, Posterior spine to greater sciatic buttress; 6, Posterior column. (a–c reprinted with permission from Letournel and Judet.[11] d reprinted with permission from Letournel.[51])

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FIGURE 7.5. Uni- and bilateral longitudinal sacral fractures for which iliosacral fixation is feasible. (a) Posterior view. (b) Anterior views. (c) Reduction with tenaculum forceps. (d) Insertion of screws in posterolateral ilium.

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Vascular Anatomy of the Pelvis

A knowledge of the vascular supply of the pelvic region is crucial for the recognition of sites of potentially massive hemorrhage accompanying a pelvic disruption, for potential iatrogenic injury to major pelvic vessels, and for compromise of the nutrition of the pelvis with surgical reconstruction.[12] In the false pelvis, the common iliac vessels divide into the internal and external iliac branches. With severe pelvic trauma, that nevertheless is consistent with a viable patient, these major vessels rarely are damaged. When the common, internal, or external iliac vessels are disrupted, urgent identification and a direct surgical repair of the vascular disruption provides the only likelihood for survival. At the pelvic brim, the internal iliac artery divides into anterior and posterior divisions. Typically, the latter subdivides into the superior gluteal, iliolumbar, and lateral sacral arteries. With posterior displacement of the hemipelvis, an injury to the posterior division and/or superior gluteal artery is likely to ensue with the potential for major hemorrhage and compromise of the viability of the gluteus medius and minimis. The anterior division possesses many branches including the internal pudendal, inferior gluteal, and obturator arteries. Injury to these 3-mm vessels, likewise, can be followed by significant hemorrhage. An extensive venous plexus, accompanying the pelvic arteries, also is vulnerable to injury with a pelvic disruption.

At the time of surgical reconstruction of a pelvic or acetabular fracture, preservation of the blood supply of each major bony fragment is crucial to facilitate healing and afford resistance to infection. On the inner surface of the anterior ilium and iliac crest, nutrition is provided by the deep circumflex iliac artery, a branch of the external iliac artery. A still larger nutrient foramina is situated in the internal iliac fossa, 1 cm anterior to the surface of the sacroiliac joint and 1 cm superior to the iliopectineal line, where it receives a branch from the iliolumbar artery. On the external surface of the bone, a large nutrient foramen is observed in the middle of the gluteal area of the iliac wing, which receives a branch from the superior gluteal artery. Supplementary vascular supplies include multiple nutrient vessels around the acetabular margin, which form a complete vascular circle arising from the obturator and the superior and inferior gluteal arteries. The sciatic buttress receives numerous branches from the superior gluteal artery.

Major Nerves Adjacent to the Pelvis

Virtually all portions of the lumbosacral and coccygeal plexuses may be injured by pelvic trauma. The lumbosacral and coccygeal nerve plexuses are derived from the anterior rami of the T-12 to S-4 spinal nerves.[13] The L-4 to S-1 segments are particularly prone to injury including the femoral nerve (Figure 7.6). After the lumbosacral trunk and the first sacral root unite anterior to the sacroiliac joint, they join with S-2, S-3, and S-4 anterior to the piriformis. The common outflow divides into two terminal branches, the sciatic and pudendal nerves, and supplementary branches including the superior and inferior gluteal nerves. Many branches pass through the greater sciatic notch, notably the sciatic nerve, which forms the largest branch of the sacral plexus. The sciatic nerve exits the pelvis between the inferior border of the piriformis and the ischial border of the greater sciatic notch. It possesses two divisions, the tibial and peroneal, which are loosely bound together. The nerve is vulnerable to injury, especially with a posterior dislocation of the hip or a posterior acetabular fracture. The peroneal division is particularly susceptible to injury and less likely to recover. The principal L-5 root contribution to the peroneal division is vulnerable to injury at the root level, both behind the hip joint and where it exits the greater sciatic notch. The superior gluteal nerve (L-4 to S-1) is susceptible to injury with posterior approaches to the hip and acetabulum. Typically, such a traction injury is associated with the insertion of a retractor or a lengthy plate on the posterior column. With anterior or ilioinguinal approaches, the lateral femoral cutaneous nerve of the thigh is vulnerable to a laceration or to a traction injury. When an ilioinguinal incision is used to expose an extensive acetabular fracture, typically some

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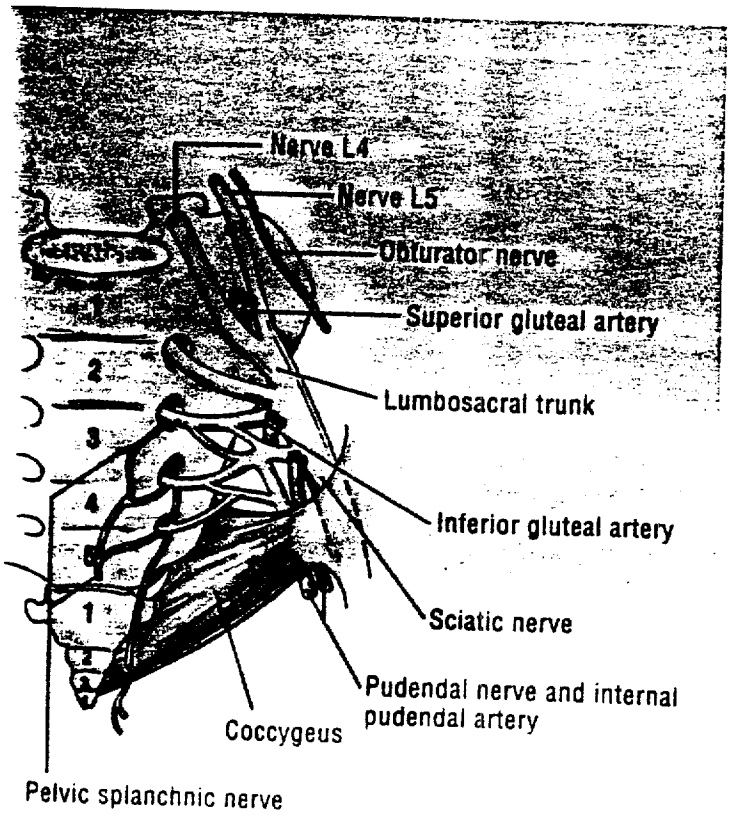

FIGURE 7.6. The sacral plexus and origin of the sciatic nerve. (Reprinted with permission from Agur.[12])

degree of hypesthesia of the anterior thigh ensues.

Assessment

Before definitive treatment of a pelvic or acetabular fracture is initiated, the injury is rigorously characterized by its clinical and radiographic features.[14,15] The direction of the provocative forces may be obtained from the history of an alert patient and from clinical inspection for sites of contusion or ecchymosis. The history of a motor vehicular or industrial accident should alert the surgeon to the high likelihood for the presence of a major unstable pelvic injury and the potential for concomitant visceral or neurovascular insults. The pelvic region is examined for evidence of asymmetry, instability, or the presence of an open wound. A laceration in the groin, scrotum, or peroneal region or of the vagina and rectum is highly suspicious of an open pelvic fracture. An apparent deformity of the lower extremity in the absence of a fracture in the lower limb may indicate a pelvic fracture

In the presence of hemodynamic instability, the initial radiographic assessment of the pelvis may be limited to an anteroposterior view. Subsequently, precise characterization of the injury necessitates a minimum radiographic protocol of anteroposterior, inlet, and outlet views. For the inlet view of the supine patient, the x-ray beam is directed from the head to the mid-pelvis at about 45° with respect to the radiographic table.[15,16] Such a projection is perpendicular to the pelvic brim and illustrates the true pelvic inlet, as well as the anteroposterior displacement

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of the pelvic fracture. To obtain an outlet projection of a supine patient, the beam is directed from the foot to the pubic symphysis at 45° with respect to the radiographic plate. The outlet projection highlights superior displacement of the posterior half of the pelvis, as well as superior or inferior displacement of the rami. Apparent limb length discrepancy secondary to a sagittal malrotation of a hemipelvis is highlighted, along with avulsion fractures of the transverse processes of the lower lumbar vertebrae or ramus fractures. For an acetabular disruption, special Judet or obturator and iliac oblique views are obtained by rolling the injured patient carefully from one side to the other to provide a transverse axis of the pelvis of 45° relative to the radiographic table. Supplementary computed tomography (CT) is indispensable to document sites of pelvic disruption, displacement, and comminution.[17] A sacral fracture that is virtually invisible on plain radiographs is readily documented by resort to computed axial tomography. The degree of separation and instability of a sacroiliac joint or sacral fracture is evident.

Five standard coronal sections are taken at intervals of about 2 cm. The most superior section projects the iliac wings and the adjacent sacroiliac joints. The second highlights the principal part of the sacrum and adjacent sacroiliac joints. The third displays the dome of the acetabulum with a circular cross section. The fourth transects the mid-acetabular region and includes a midpolar view of the femoral head, whereas the fifth documents the inferior pubic ramus and the ischial tuberosity at the level of the greater trochanter. Where surgical reconstruction of a comminuted and displaced pelvic or acetabular fracture is anticipated, an accurate three-dimensional (3D) radiographic perspective is extremely valuable to define the optimal surgical approach, the strategy for the open reduction, and the preferred method of fixation. When reviewing the conventional two-dimensional radiographs and CT scans, even an experienced surgeon has difficulty with the extensive mental integration needed to achieve an accurate three-dimensional image of the injury. Typically, the displacement of the major fracture fragments is primarily a rotational distortion that further complicates the mental imaging. Computer programs are available to produce three-dimensional surface reformations from sets of contiguous axial computed scans of the pelvis.[18,19] The images can be obtained within 1 to 12 hours after the arrival of the patient in the radiographic suite. While the 3D CT images can be created from virtually any angle of scrutiny, a standard pelvic series comprises the anterior, posterior, superior, and inferior orthogonal views and the inlet and outlet 45° oblique projections. Also, the 45° oblique views comprising the iliac and obturator oblique projections display the internal and external surfaces of the acetabulum. A special "dome view" is obtained from a projection approximating 20° inferior and 20° anterior to the true lateral view. After a subtraction, or so-called disarticulation, of the femoral head, the last view presents the acetabulum as a true hemispherical recess and provides a clearer view of the acetabular dome, as well as the medial, anterior, and posterior walls.

Classification of Injuries

Pelvis

Pennal, Tile, and associates[20] classify the principal pelvic ring disruptions based upon the direction of the provocative force and the degree of pelvic disruption. Injuries may result from provocative blows that impose anterior-posterior or lateral compressive forces on the pelvis or from falls or other unusual injuries that exert vertical shearing forces on the pelvic ring. This classification provides insight into the nature of the injury, the morbidity, the potential sites of disruptions, the degrees of pelvic instability, and recommendations for treatment. An anterior posterior compression injury, also known as an external rotation deformity, results from a blow that strikes the posterior ilium or the anterior pelvis to disrupt the symphysis and the anterior sacroiliac ligaments of one or both sacroiliac joints. Usually, the crucial posterior sacroiliac complex is spared so that the injury is vertically stable. Not infrequently the ipsilateral floor of

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the hemipelvis, including the sacrospinous and sacrotuberous ligaments, is compromised so that a modest sagittal malrotation of the hemipelvis ensues.

A lateral compression injury arises from a direct blow to the lateral ilium, typically to provoke an extremely unstable impacted fracture of the sacrum. Most typically, an accompanying anterolateral rotational force provokes an inward rotation of the ipsilateral hemipelvis, so that the ipsilateral pubic rami, or occasionally all four rami, are disrupted with some overlapping of the fracture fragments.

A vertical shear injury is a highly unstable disruption with complete posterior ligamentous instability of one or both sacroiliac joints. Most of the patients are victims of falls from a great height or of high-speed crashes. Usually, the associated anterior disruption is a diastasis of the symphysis pubis. Supplementary radiographic findings include avulsion fractures of the sacrospinous and sacrotuberous ligaments from the ischial spine or the adjacent sacrum, as well as avulsion fractures of the transverse processes of the fourth and fifth lumbar vertebrae.

Acetabulum

Currently, the most widely employed classification scheme of acetabular fractures is that devised by Letournel and Judet.[11,21] These workers identified two major categories of elementary and associated fractures. In an elementary fracture, all or part of one column is involved to provoke a posterior wall, posterior column, anterior wall, or anterior column fracture. One other elementary pattern is a transverse fracture in which the superior acetabulum is separated from the inferior portion. The associated fracture patterns include any two of the elementary forms. The five principal examples are a fracture of the posterior column and posterior wall, a transverse and posterior wall fracture, a T-type fracture, a fracture of the anterior column and anterior wall associated with a hemitransverse fracture posteriorly, and a complete both-column fracture. The last example is where all of the articular surface is disrupted to create at least three major fracture fragments. Characterization of the injuries by these patterns provides insight into the optimal surgical approach and a guideline to prognosis with or without surgical reconstruction.

Acute Management

The management of a patient with a pelvic ring or acetabular disruption is logically divided into two principal phases.[22] During the first phase of acute resuscitation, diagnostic and therapeutic measures are initiated. A multidisciplinary protocol is needed to define the priorities of diagnosis and therapy involving the general surgical, orthopaedic, urologic, and neurosurgical members of the trauma team. Quantitative assessment of the extent and severity of the injuries using an injury-severity scale is strongly advised. The conventional priorities of acute therapy are repair of respiratory, cardiovascular, central nervous system, urologic, gastrointestinal, and musculoskeletal systems. In the presence of hemodynamic instability, a definitive diagnosis and stabilization of the pelvis is deferred. In the other patients, a complete diagnostic survey of the pelvis can be undertaken soon after admission. In either event, the goals of management include anatomical restoration of the pelvis with sufficient stability so that the patient can be mobilized to at least a bed to chair existence, if not a partial weight-bearing gait. Surgical reconstruction should provide substantial alleviation of fracture pain and sufficient mobilization to facilitate pulmonary toilet, general patient care, and expeditious discharge from the hospital. Acute stabilization of a displaced injury minimizes the likelihood for a catastrophic late problem such as a painful nonunion or malunion of the pelvis.

Definitive Stabilization

The preferred techniques for stabilization of the pelvis and acetabulum remain controversial in a field that is evolving very rapidly. While diverse therapeutic protocols are available, certain features of any acceptable format can be clearly defined. An algorithm for pelvic stabilization

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should outline a suitable technique for the fixation of virtually any type of pelvic ring disruption or acetabular fracture.[23] Such an algorithm needs to provide viable therapeutic options, depending upon the sites of open pelvic wounds, a diversion colostomy or a urinary drainage, as well as the diverse injury patterns, the varying amounts of comminution, and the degree of osteopenia. For the pelvic ring, historically external fixation evolved as the first definitive method to address a variety of disruptions with moderate instability of the posterior pelvic ring. During the past decade, a rapid increase in the clinical application of techniques of internal fixation has occurred as surgeons recognized the superior mechanical stability afforded by internal fixation of unstable injury patterns. Also, the availability of percutaneous lag screws has created a stable method of internal fixation that necessitates minimal surgical exposure. As the number of pelvic injury sites increases, the need for rigorous internal fixation rapidly accelerates. Ironically, the most complicated cases have the greatest absolute indication for technically demanding surgical reconstruction. Especially in a community hospital or a tertiary center with limited experience in pelvic reconstruction, many of the complicated cases merit referral to a regional trauma center where the appropriate surgical training and instrumentation are available.

Indications for Internal Fixation of the Pelvic Ring

Currently, the indications for the application of internal fixation to an unstable pelvic ring disruption remain highly controversial. Most surgeons agree that stable injuries with minimal instability and minimal pelvic deformity merit conservative treatment. Once the pelvic ring is traumatically rendered unstable and deformed, the questions arise about the degree of instability and deformity that constitute indications for internal fixation. The enthusiasm for surgical reconstruction has to be tempered by the potential for surgical complications and the 40% incidence of late posterior pelvic and low back pain that ensues even when an accurate stable internal fixation is achieved without a surgical or iatrogenic complication. For unstable pelvic injuries that are managed by external fixation, Riemer and Miranda[24] report that the results documented at late outcome, in terms of the amount of pain, functional incapacity, and return to gainful employment, are equivalent to those documented after the use of internal fixation. Where the least doubt about the role of internal fixation exists is with respect to bilateral unstable posterior injuries and other complex injury patterns where isolated external fixation has no potential to stabilize the pelvic ring with respect to the spine.

Probably at least half of the patients who sustain a pelvic injury present with a minimally displaced fracture, especially following a low-velocity lateral compressive force. Another example is a diastasis of the symphysis with less than 2 cm of displacement. In these instances, temporary bed rest followed by partial weight bearing for a few weeks is usually sufficient treatment. Another large subcategory includes a diastasis with greater than 2 cm of displacement of the symphysis, when surgical stabilization is recommended. Plate fixation of the symphysis through a limited anterior exposure is the method of choice. While plate fixation can be applied to anterior ramus fractures, the surgical approach across the inguinal region is moderately difficult and potentially hazardous. Generally, external fixation is preferred to manage an anterior injury with multiple displaced ramus fractures. One exception is the presence of displaced rami in a young female. In this instance, a persistent nonunion or malunion of the rami often leads to dyspareunia or the need for a cesarean section at the time of delivery. With an open reduction, an accurate reconstruction of the anterior pelvic ring can provide a minimal risk for the late obstetric and gynecological complications.

A second category of displaced pelvic disruptions with posterior instability follows a dislocation of the sacroiliac joint or a fracture of the neighboring portions of the posterior ilium or sacrum. Typically, an anterior accompanying injury involves a diastasis of the symphysis or ramus fractures. In such an example, the pelvic

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ring can be perceived as having three supportive columns of bone.[25] The anterior column refers to the symphysis and the adjacent superior pubic rami. The middle column refers to the body of the sacrum, the adjacent portions of sacroiliac joints, and the allied posterior ilium. The posterior column refers to the posterior elements of the sacrum and the neighboring portions of posterior ilia via the posterior superior spine. Two of the three columns are immobilized with internal fixation. Typically, the anterior column injury is surgically exposed, reduced, and plated. This maneuver generally provides a satisfactory reduction of the posterior injury. As an alternative, anterior column fixation can be afforded by a simple external frame that spans from half pins inserted into either anterior iliac crest. Subsequently, either the middle column is stabilized with lag screws or anterior plates, or the posterior column is immobilized with a plate. In osteopenic individuals, and especially the elderly, usually the rami afford insufficient structural integrity to merit plate fixation. In such an instance, the middle and posterior columns are immobilized as the preferred strategy of fixation.

A third major category of pelvic fracture is a complex ring disruption. The largest group is a family of bilateral posterior unstable injuries with a combination of sacroiliac dislocations or unstable fractures involving the sacrum or posterior ilium. Another pattern is where an unstable posterior fracture dislocation is accompanied by an acetabular fracture as well as an anterior injury. Still other cases involve multiple combinations of posterior, unstable injuries and bilateral acetabular fractures. All of these injuries may have various combinations of anterior disruption. Typically, each unstable site merits an open reduction and internal fixation. With ipsilateral superior and inferior ramus fractures, however, generally only the superior ramus is immobilized. By resort to a bilateral ilioinguinal surgical exposure, the rami and symphysis, as well as the lateral ilium and sacroiliac joint, can be exposed for the reduction and fixation. As part of the procedure, percutaneous lag screws can be utilized to stabilize the sacral body. A supplementary surgical approach may be necessary to expose an accompanying fracture of the posterior acetabular wall or column or a displaced sacral fracture

Indications for Acetabular Fixation

Currently, for most displaced acetabular fractures in young adults or children, an open reduction with internal fixation is recommended.[26] Posterior fracture dislocations and transverse fractures have a particularly poor outlook unless an accurate reduction is achieved. Certain both column fractures possess so-called secondary congruity, whereby the fracture fragments rotate around the femoral head to maintain a spherical bearing surface. Of the significant displaced acetabular fractures, this injury pattern possesses the best outcome following the application of nonoperative methods. Particularly in the elderly with marked comminution, osteopenia, and associated medical problems, conservative management of such an injury may be preferred. A small spectrum of acetabular fractures are notable for marked impaction or abrasive damage to the bearing surfaces or occasionally other problems such as late presentation, morbid obesity, and concomitant medical problems, where conservative management is doomed, and yet an open reduction and internal fixation is impractical or impossible. An acute total hip joint replacement may be the best current option for those uncommon cases.[27] For the acetabular component, an associated metal cup with an outer porous coating for bony ingrowth and with the capability for the insertion of multiple screws serves as a hemispherical plate. The femoral head can be morselized for bone graft, or it can serve as a structural graft for augmentation of the posterior wall or dome. The major acetabular fragments can be reduced through a relatively limited and conventional total hip exposure. Supplementary lag screws can be used to immobilize large extraarticular fragments such as a large portion of the anterior ilium and iliac crest. Usually, such screws are inserted through small additional incisions, frequently superficial to the anterior superior and anterior inferior iliac spines.

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Contraindications for Internal Fixation of the Pelvis and Acelabulum

In the presence of an unstable pelvic fracture, most contraindications to internal fixation are of a transient nature. With hemodynamic instability or other acute medical problem, deferral of a major pelvic reconstruction may be necessary. In the presence of an open pelvic fracture, especially with fecal contamination, transient external fixation may be preferred while diversion of the bowel and cleansing of the wound are undertaken. Typically, within a few days, internal fixation of the pelvic ring, by resort to cannulated lag screws, especially of the critical posterior portion, can be undertaken by the use of a limited surgical exposure somewhat remotely situated with respect to the colostomy or an open wound. In cases of late presentation, assessment referable to the assets and practicality of surgical reconstruction merits special consideration. Factors under review will include the acceptability of the deformity, the potential for spontaneous union and stability of the pelvic ring, the degree of technical difficulty and, especially, the presence or risk of complicating features such as massive heterotopic bone.

Complications of Internal Fixation of the Pelvis and Acetabulum

A principal source of complications of internal pelvic fixation is related to the particular surgical exposure. The juxtaposition of major neurovascular structures, as well as the intraabdominal viscera, combined with most orthopaedic surgeons' limited familiarity with the pelvic region, provides a special likelihood for allied complications. This problem is further aggravated if the surgery is undertaken after a delayed presentation. Scarified boundaries, the presence of heterotopic bone, and abnormalities such as traumatically induced urinary diverticula create particularly hazardous conditions. A second family of complications is related to the surgical reduction. A traction injury to the sciatic nerve is perhaps the best-known problem following a posterior fracture dislocation of the hip. Where the sciatic nerve is contused at the time of the traumatic injury, subtle features of nerve deficit, including mild hypesthesia of the second and third toes or a corresponding mild weakness of the extensor digitorium longus, may be the only sign of the potential impending catastrophe.[28] With even a limited surgical manipulation of the nerve or limited retraction, it is susceptible to frank deterioration in function to culminate in a complete foot drop, with hypesthesia of the foot and a potential for late dysesthetic pain in the lower leg and foot. The use of intraoperative somatosensory evoked potential monitoring permits the recognition of such a susceptible nerve and the potential for rapid correction of the provocative surgical maneuver.[29,30]

The third family of complications is related to the application of the fixation devices. The guide wires or drill bits that are used in conjunction with cannulated screws are particularly hazardous, especially if the far cortex of bone is breached. Many columns of pelvic bone, such as the superior pubic ramus, are relatively small so that the target area is limited. Alternatively, in the sacrum, the presence of nerve roots in the foramina provides a source of neurological hazard that is in close proximity to the limited available bone stock. A fourth category pertains to a postsurgical problem such as problematic wound healing, heterotopic bone around the acetabulum after a lateral surgical exposure, avascular necrosis of the femoral head or acetabulum, and a late nonunion or malunion.[31] Many of these problems represent complications that follow excessive stripping of soft tissue and devascularization of the bone fragments. To minimize the risk of heterotopic bone, several strategies are available. When an anterior ilioinguinal approach is used, the risk of significant heterotopic bone is minimal. For a high-risk patient, especially a large obese male who has sustained an accompanying closed head injury, an extended lateral surgical approach to the acetabulum should be avoided if at all possible. From the time of surgery, indomethacin can be given as a prophylactic agent. Alternatively, postoperative irradiation therapy of 700 to

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1,000 C Gy can be given as a single pulse or in subdivided doses.[32]

Intraoperative Imaging Techniques

Currently, intraoperative imaging of the pelvis and acetabulum is a critical part of most reconstructive procedures. The accuracy of a reduction can be assessed. Minimally invasive fixation, especially by resort to cannulated lag screws, can be utilized. The presence of a screw violating the hip joint or a foramen can be documented so that a timely corrective measure follows. To facilitate the intraoperative imaging, the use of the Jackson graphite composite operating table is strongly preferred. The completely radiolucent table is supported at the top and the bottom so that the central region beneath the pelvis is totally accessible for a C-arm. The newest version of the table permits the application of longitudinal or lateral traction. In conjunction with the table, a modern C-arm image intensifier with a 9-inch field size is recommended. The Siemens and O.E.C.-Toshiba models possess a high resolution and large field size for satisfactory visualization. Once the patient has been anesthetized and positioned on the tables and prior to draping the patient, a trial rehearsal of the relevant imaging techniques is performed. Where the x-ray technician possesses less than optimal training, this rehearsal period enables the surgeon to educate the technician, while the position of the patient is clearly evident. When necessary, the position of the patient can be modified somewhat to optimize the field for imaging.

Where high-resolution imaging is needed, towel clips are secured where they will not compromise the field of imaging. Typically, the clips are positioned sufficiently superior and inferior so that they are out of the radiographic field. Within the surgical field, supplementary skin staples or sutures are used to secure the drapes. As a third method, plastic adhesive barrier drapes are used to anchor the cloth drapes. After the patient has been draped, another scout image with the C-arm image intensifier is obtained to ensure the absence of the towel clips and other artifact from the field of interest. During the surgery, the anterior-posterior, inlet, and outlet views, as well as the Judet views, are obtained. For the documentation of an iliosacral screw, a supplementary direct lateral sacral view is necessary.

Mechanical Criteria for Pelvic Fixation Devices

The optimal mechanical behavior of fixation devices for use on the pelvis is quite different from the criteria for devices that are designed for application on the appendicular skeleton. With its ring-like nature, the pelvis is not subject to bending stresses that rival loads imposed upon long bones and the allied fixation.[9] When plates are applied to the curved surfaces of the innominate bone, contouring of the plate to fit accurately to the osseous surface becomes a major concern. If a plate is rigid, even a minor error in the contour will provoke a displacement of an anatomically reduced fracture when the corresponding screws are tightened. Flexibility of the plate, thereby, represents a significant attribute. As with all fracture fixation hardware, an ability to tolerate fatigue forces imposed by the presence of a delayed union is valuable. After surgery, the use of standard transaxial CT or 3D CT for the scrutiny of the reduction and the position of the hardware is very helpful, especially for cases where a screw approximates the hip joint or a foramen. From all of these points of view, a titanium alloy, such as 6% aluminum and 4% vanadium, is the optimal material for plates and screws, and possesses a marked superiority over surgical grade stainless steel. Reconstruction plates with oval holes or slots permit the optimal deviation of the screw away from the axis of the plate. For most applications of a plate around the acetabulum, a 3.5- or 3.7-mm size in terms of adequate strength and ductility is preferred. The screws are of 3.5- or 3.7-mm cortical or 4.0-mm fully threaded cancellous designs and ideally of a self-tapping configuration. Lengthy screws of up to 120 mm

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are needed. Particularly for longer screws, power insertion is recommended. For application in deep wounds consistent with pelvic incisions, special long drill bits and drill sleeves are needed. For the immobilization of the posterior portion of the pelvic ring, 4.5-mm reconstruction plates are preferred, along with 4.5-mm cortical or 6.5-mm cancellous screws. Such a plate can be contoured to fit across the back of the sacrum and adjacent ilia as a tension-plate configuration.[33] For fixation of the front of the sacroiliac joint, 4.5-mm screws can be inserted through 4.5-mm or ideally 3.5-mm plates of two holes. The plates are directed across the alar region of the sacroiliac joint with the screws oriented parallel to the axis of the joint. With the 3.5-mm plates, the screws are closer together and tend to be directed along the narrow juxtaarticular region of the thick bone that is free of a neural foramen. In contrast, a 4.5-mm plate possesses a wider interspace between the holes. Either the medial end of the plate is liable to injure the L-5 nerve root or the lateral end is situated above the thin portion of lateral ilium. In the latter case, the fixation is significantly compromised by the corresponding short screws (Figure 7.4c). Special anterior sacroiliac plates are available that effectively link two short conventional plates in an H-like design. With their added cost and limited utility, probably the H-plates are not cost-effective.

For the thin portions of the posterior and anterior wall of the acetabulum, specialized plates have been devised that permit a buttressing of the bone with a minimal risk for a screw to penetrate the hip joint. Such a spring or hook plate design was popularized by Mast et al.,[34] and assessed biomechanically by Goulet et al.[35] A short one-third tubular plate of 3.5-mm size and typically of three holes in length is trimmed to prepare two pointed spurs at one end. The pointed ends are bent by 90° to create hooks. The plate is contoured with a gentle convexity away from the bony surface. As screws are inserted into the apex of the curve and at the end of the plate remote from the hip joint, the hooks engage the juxtaarticular wall to buttress it. Assemblies of one or more hook plates can be combined with a conventional reconstruction plate and are fashioned to immobilize comminuted segments of the posterior or anterior column and wall.

Cannulated Screws

The 7.0- and 4.5-mm cannulated screws are particularly suitable for fixation of the posterior hemipelvis and acetabular region, respectively. The larger screws are preferred for the posterior ilium, sacroiliac joint, and sacral body, whereas the smaller ones are effective for fixation of the anterior and posterior columns and adjacent structural columns neighboring the acetabulum. In the biomechanical studies in pelvic ring and acetabular fixation performed by Sawaguchi et al.,[9] and by Rubash et al.,[36] the optimal characteristics of screws for strength and holding power were defined. As a generalization, longer screws of a small diameter are particularly effective in the pelvis. For younger adults, cortical screws realize as effective a fixation as cancellous screws. Admittedly, these studies did not evaluate cannulated screws. For lag screws, generally a thread length of 32 mm or more is preferred. For the lengthy screws of 90 to 150 mm that transfix the sacral body and occasionally both sacroiliac joints, excessive flexibility of a guide wire is potentially a great problem. A guide wire of 2.0-mm diameter is highly vulnerable to bend as it penetrates the iliac or sacral subchondral bone as it crosses the sacroiliac joint. The optimal range of guide wires is 2.8 to 3.2 mm in diameter. While the 3.2 mm is highly rigid, it presents a concern that excessive heat might be generated during its insertion so that thermal damage of an adjacent nerve root could occur. The author has assessed a 7.2-mm design with a 2.8-mm cannula. The tip of the screw is designed for self-drilling and self-tapping. Both threaded tip guide wires and small drill bits are available as a pilot for the screw. Associated tools include a depth gauge and a set of drill sleeves. A supplementary drill sleeve permits the insertion of two 7.2-mm screws in parallel, divergent, or convergent alignment. The 4.5-mm screws possess a similar collection of tools. During insertion, undulation of the smaller, but shorter guide wires has not been a problem.

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Indications For the Use of Cannulated Lag Screws in the Pelvis

The attributes of a cannulated screw for pelvic fixation pertain to a minimally invasive or percutaneous method of fixation and the preliminary insertion of a small guide wire under image intensification for penetration of a column of bone that is of a small diameter or that is adjacent to vulnerable soft tissue, especially nerves. In the latter situation, when a conventional drill bit is replaced with a screw, the screw has a potential to follow an errant pathway with possible damage to associated tissues that cannot occur when the screw is driven over a guide wire. While a cannulated screw of a given core and outside diameters is of somewhat lesser static and fatigue strength than a solid counterpart, in clinical practice, this feature is a minor liability.[37] Currently available designs of cannulated screws possess an enlarged core diameter so that breakage of screws has not been a significant problem. During the insertion of a cannulated screw, the surgeon needs to have a firm grasp of the anatomical landmarks and must obtain a variety of special radiologic views on the image intensifier that permits a documentation of a safe and appropriate insertional pathway.

Fixation Techniques for Particular Sites

The Sacroiliac Joint

Cannulated lag screw fixation can be undertaken for a subluxed or dislocated sacroiliac joint. In the former case, the anterior aspects of the joint are separated, possibly with a limited accompanying sagittal or coronal rotational deformity. In the latter situation, the articular surfaces are displaced in a multiplanar fashion that renders the joint highly unstable unless an accurate reduction is achieved. Where cannulated screws are selected for fixation, the crucial recognition is that the operative procedure needs to include some method for accurate reduction of the joint (Figure 7.7). Where the anterior injury is a diastasis, the open reduction of the symphysis may facilitate a corresponding reduction of the sacroiliac joint so that percutaneous fixation with cannulated screws is feasible. For a late presentation, more than a week after the injury, and where skeletal traction was not used to control the initial deformity, an open reduction by resort to an an anterior approach of the sacroiliac joint affords the optimal view to facilitate the reduction. Once reduced, direct anterior fixation with two of the two-hole plates is readily undertaken. The use of cannulated screws for fixation is particularly attractive where a minimally displaced sacroiliac joint merits fixation c where an accurate closed reduction accompanie. the reconstruction of the anterior pelvic ring disruption. About 20% of transverse or T-type acetabular fractures are complicated by a subluxation of the ipsilateral sacroiliac joint. Prior to the acetabular exposure, an accurate realignment or fixation of the sacroiliac joint is needed to anatomically reduce the upper half of the acetabulum. While the amount of displacement of the ilium at the sacroiliac joint may appear to be inconsequential, nevertheless this amount is magnified greatly at the level of the acetabular articular surface. With the patient situated in a lateral decubitus position, the sacroiliac joint tends to spontaneously reduce so that cannulated lag screw fixation is feasible.

In the presence of marked displacement of the sacroiliac joint, an accurate reduction may be difficult or impossible to achieve by resort to a closed manipulation so that usually an open reduction is indicated. Initially, a closed reduction may be attempted as an effort to preserve the neighboring soft tissues and, especially in the presence of a diversion colostomy or an open wound where contamination of an open surgical wound represents a clinical concern (Figure 7.8). The patient is positioned in a lateral fashion to rest on the contralateral side of the pelvis. While a supine or even prone position can be used, typically the crucial reduction technique is less satisfactory for restoration of alignment of the sacroiliac joint. Image intensification with anteroposterior (AP), inlet, and outlet views is performed. The ipsilateral hip is flexed beyond 90° so that its rotation transmits a corresponding rotational force to the displaced hemipelvis. The extremity is draped and manip-

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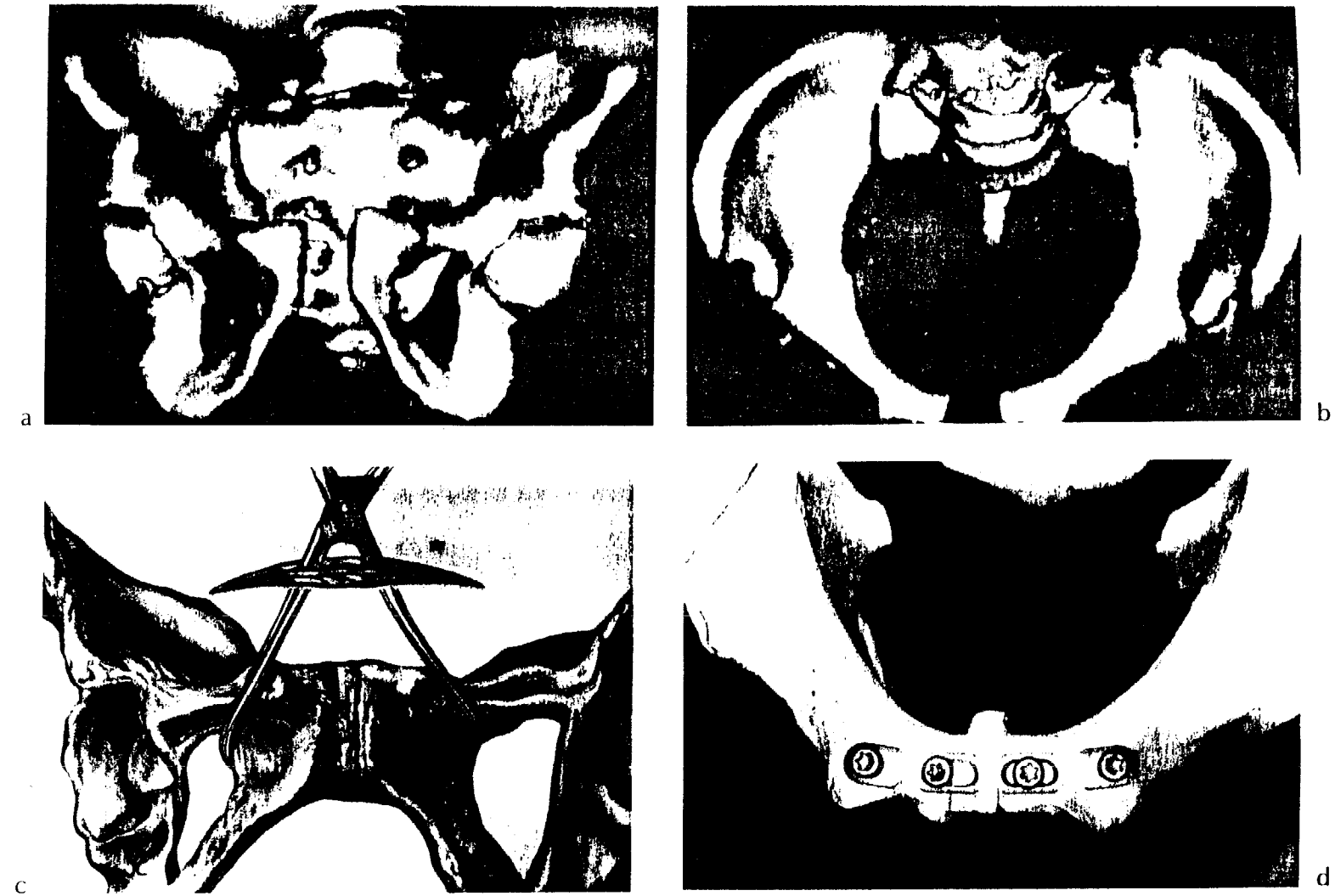

FIGURE 7.7. Technique for iliosacral fixation of external rotation injury by a percutaneous or limited open technique. (a) Anterior outlet 3D CT view. (b) Inlet 3D CT view. (c) Reduction of symphysis through Pfannenstiel approach. (d) Fixation of symphysis.

(*continued*)

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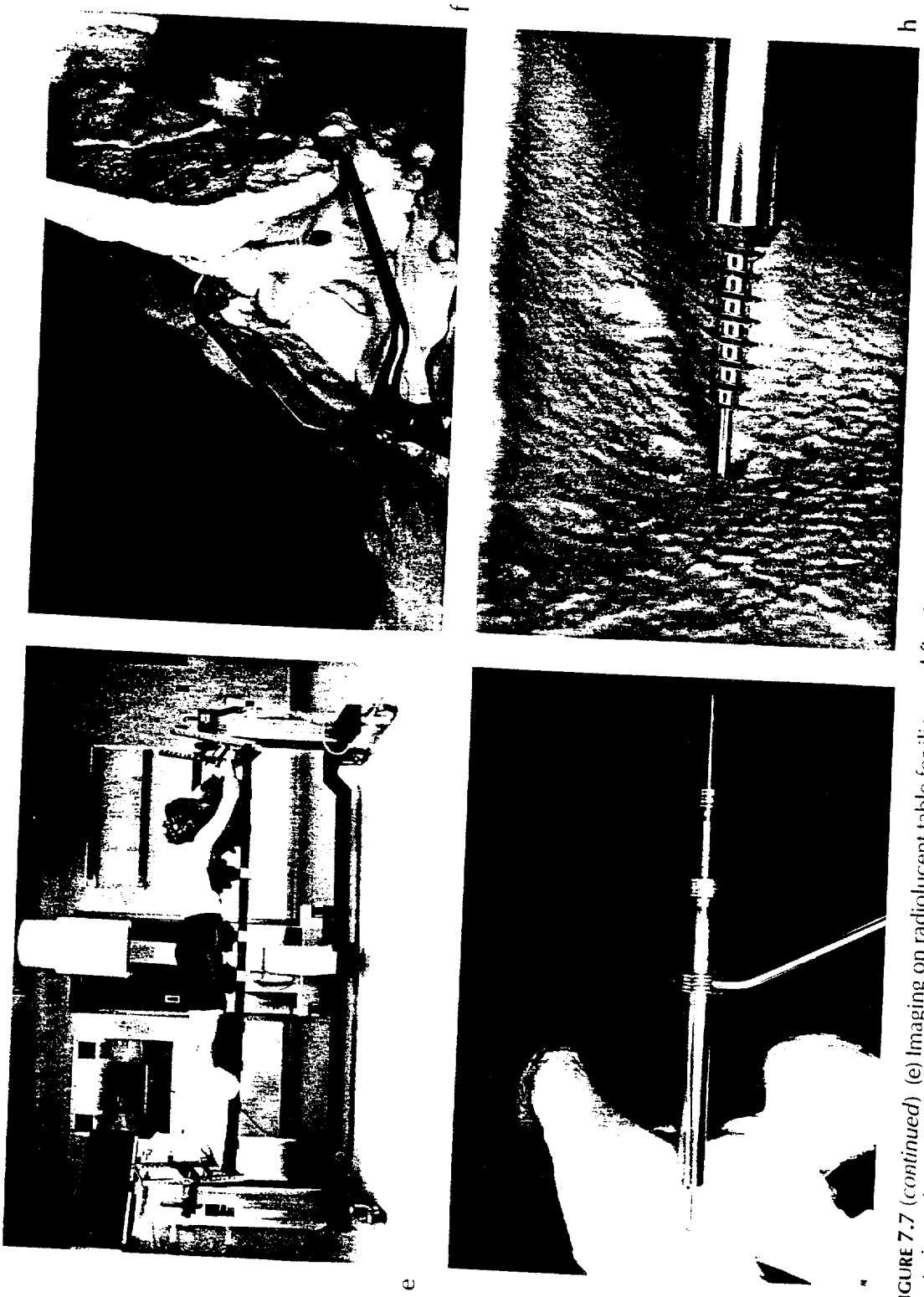

FIGURE 7.7 (*continued*) (e) Imaging on radiolucent table for iliosacral fixation. (f) Position of tenaculum forceps accompanying a limited posterior reduction. (g) Insertion of iliosacral guide wire with drill sleeves. (h) Iliosacral screw insertion.

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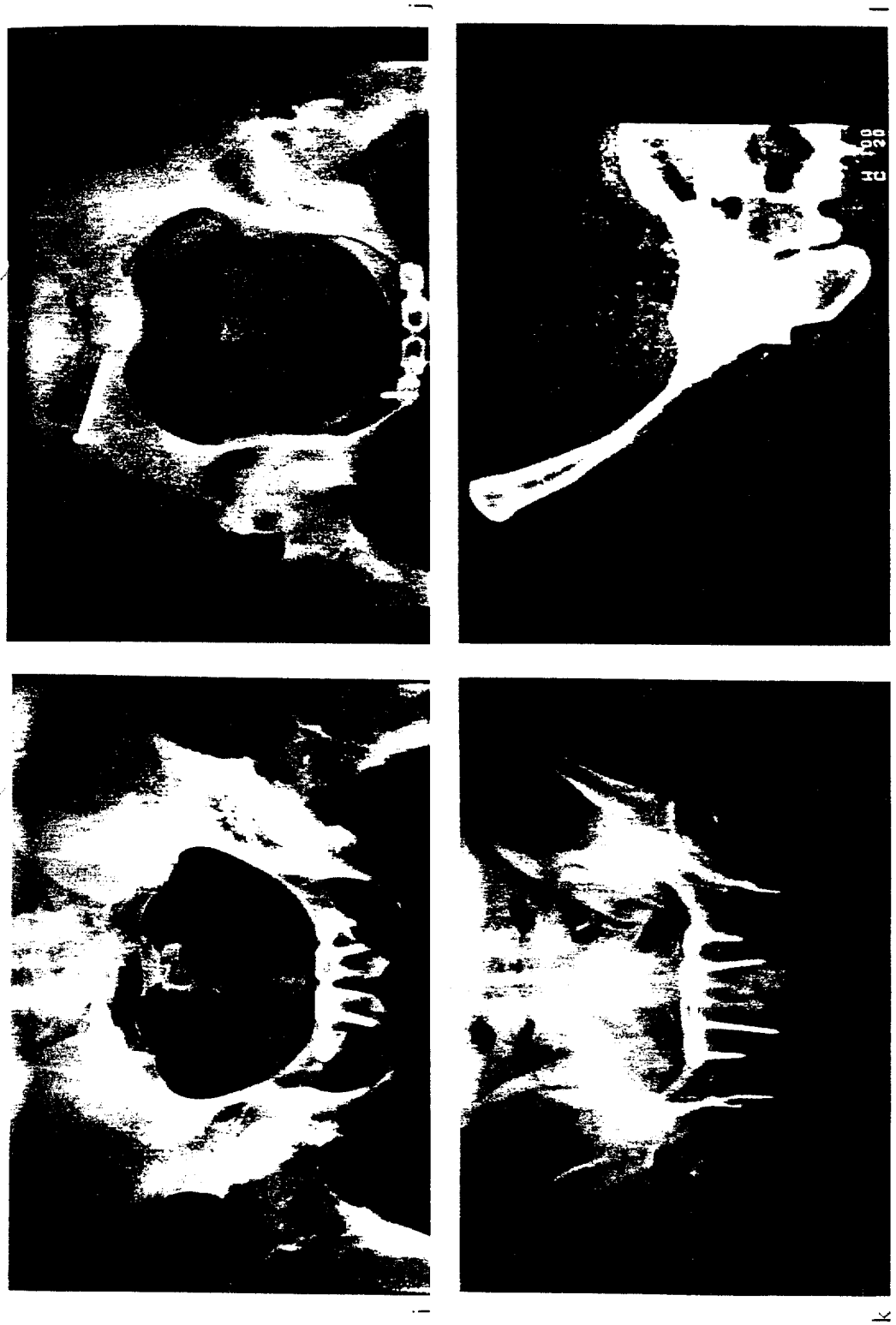

FIGURE 7.7 (i) Postoperative AP view. (j) Postoperative inlet view. (k) Postoperative outlet view. (l) Postoperative CT iliosacral view.

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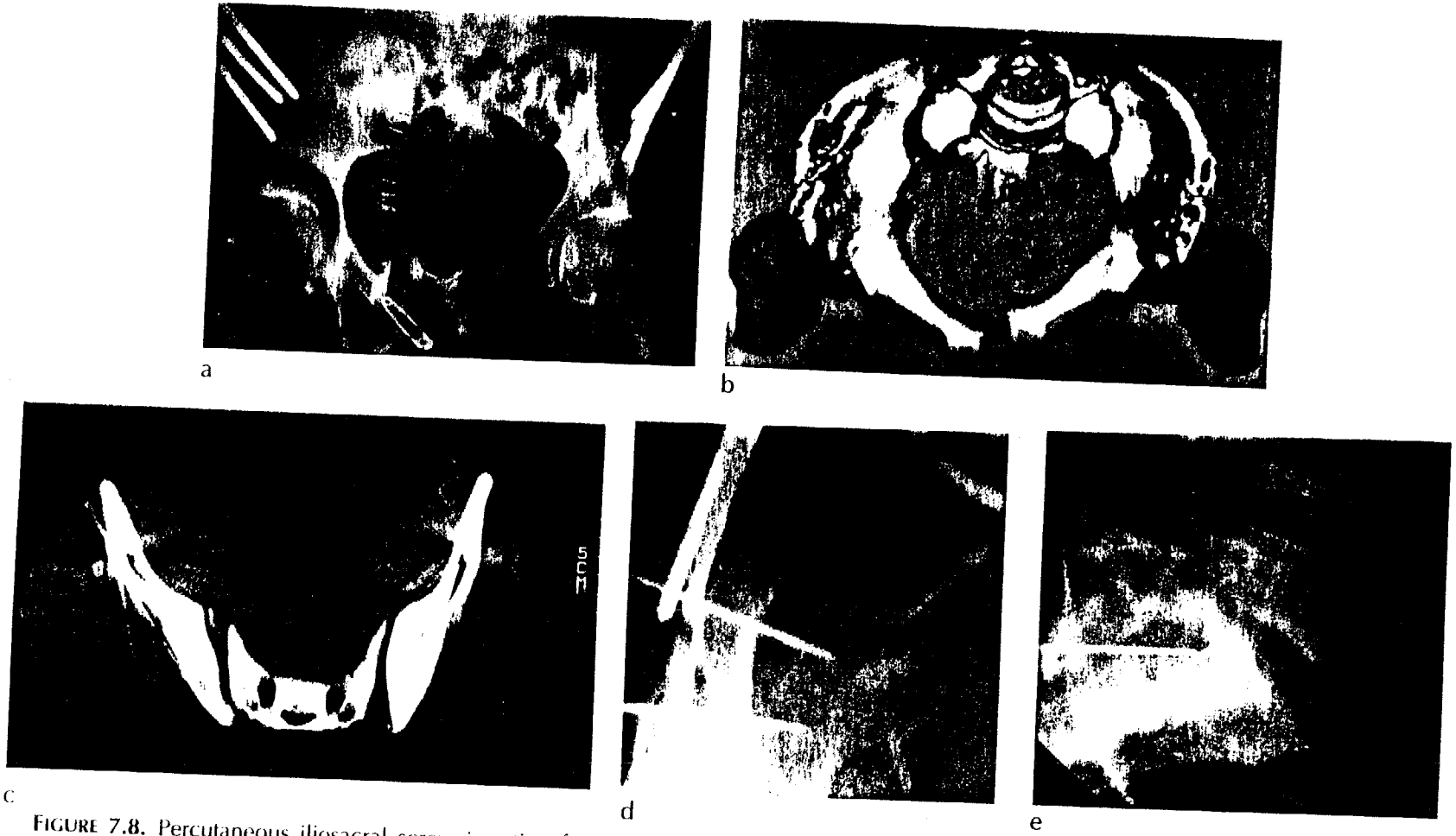

FIGURE 7.8. Percutaneous iliosacral screw insertion for a C-2 injury with a right SI dislocation and a left SI subluxation in a 28-year-old man with initial external pelvic fixation. A bladder rupture for which a primary repair was performed was complicated by dehiscence so that an open reduction of the symphysis was contraindicated. (a) Outlet view. (b) 3D CT inlet view. (c) Transaxial CT of posterior pelvic ring. (d) Intraoperative obturator oblique view of right SI joint after closed reduction with insertion of iliosacral guide wires. (e) Intraoperative direct lateral view of guide wires in S-1 body.

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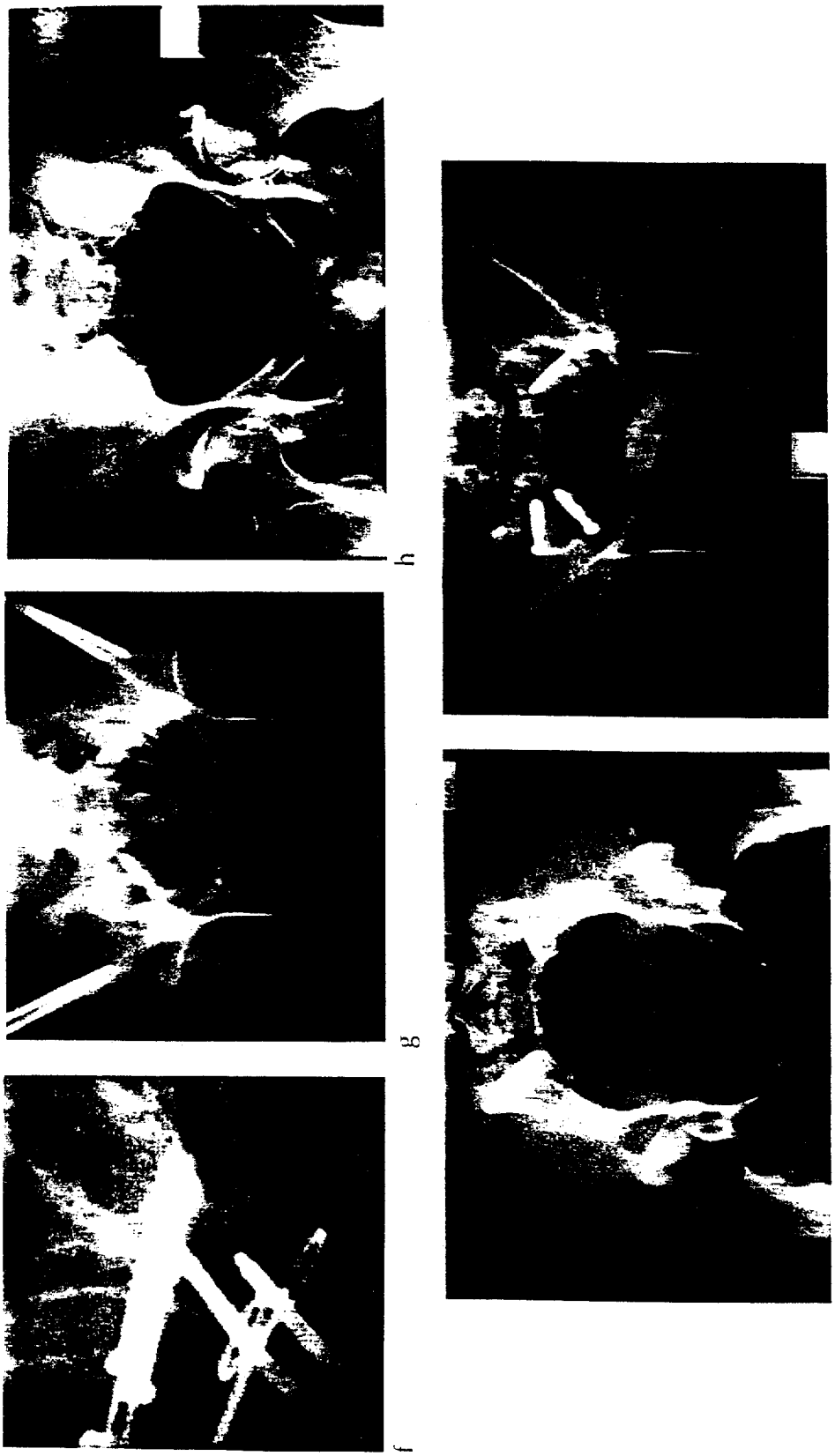

FIGURE 7.8 (f) Intraoperative obturator oblique view after iliosacral screw insertion. (g) Initial postoperative outlet view. (h) Postoperative AP view one year later. (i) Late postoperative inlet view. (j) Late postoperative outlet view.

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ulated under image intensification. Supplementary pressure can be applied on the anterior iliac crest to compress the sacroiliac joint. More effective manipulation of the hemipelvis can be achieved by the insertion of a large Schanz screw, a Steinmann pin, or external fixation pin into the anterior inferior spine, which serves as a reduction tool. Longitudinal traction can be achieved by resort to a distal femoral or proximal tibial pin. For most highly displaced sacroiliac disruptions, initially the accompanying anterior pelvic lesion, such as a diastasis of the symphysis pubis, is reduced and stabilized by an open technique. During this stage, image intensification is performed to confirm the presence of an accurate reduction of the entire pelvic ring. If the attempted anterior reduction does not reduce the sacroiliac joint, then the incision is converted into an ilioinguinal approach, and a direct open reduction and internal fixation of the sacroiliac joint is undertaken.

Percutaneous Fixation of the Sacroiliac Joint

The patient is positioned preferably prone or alternatively supine on a radiolucent table. After block draping the surgical field, a guide wire is placed transversely across the lumbar region at the level of the posterior superior spines and an AP image is obtained (Figure 7.7).

For insertion of the guide wire, a transverse incision of 1 cm in length is made at the level of the posterior superior spine. The entry point is situated where the guide wire can be directed about 10° to 20° anterior to a transaxial plane. With this orientation, the guide wire can be advanced at a right angle with respect to the axis of the sacroiliac joint. This orthogonal relationship with respect to the sacroiliac joint is further achieved if the guide wire is advanced slightly superiorward, also by about 10° to 20°. The guide wire or corresponding drill bit is advanced through the lateral iliac cortex followed by penetration of the inner iliac table of the sacroiliac joint and the adjacent sacral subchondral table. Further advancement of the guide wire into the alar portion of the first sacral body is undertaken. In most cases, the sacral penetration continues for an additional 30 to 40 mm, although the anterior sacral cortex is not breached. In this way, a long-threaded 7.0-mm cancellous screw with a length of 45 to 60 mm can be used. By penetration of three instead of four cortices, the guide wire and screw are kept within bone so that the risk of inadvertent penetration of the anterior presacral soft tissues and of the S-1 nerve root is minimized. During the insertion of the guide wire, multiple AP, inlet, and outlet views are obtained. The AP view confirms that the guide wire is inserted parallel to the transaxial plane. The outlet view permits a recognition of undesirable penetration of the superior alar surface. The inlet view is preferred for the advancement into the sacral ala toward the anterior sacral cortex.

Once the guide wire is fully inserted, a direct lateral view is taken to confirm that the guide wire remains embedded in the sacrum.[38] Particularly in an elderly individual, a large osteophyte situated along the anterior and superior border of the ala may obscure the appearance on the inlet view of excessive penetration of the guide wire beyond the anterior cortex. This problem is recognized or prevented by taking sequential lateral views (Figure 7.8). The ideal target zone for the screw thread is within the sacral ala lateral to the S-1 nerve foramina and inferior to the L5-S1 disk space. Typically, two guide wires are inserted prior to the sequential replacement with screws of appropriate length. After the use of the depth gauge, the screws are inserted while spot radiographic views are obtained to ensure that the guide wire is not inadvertently advanced during the insertion of either screw. If the guide wire bends during its insertion by even an imperceptible amount, then a subsequent binding of the screw on the deformed guide wire can provoke the undesirable advancement of the wire. Where the bone is somewhat osteopenic, a supplementary washer can be used. After tightening of the screws, an obturator oblique view is taken that is parallel to the plane of the sacroiliac joint. This image permits confirmation that the sacroiliac joint is rigorously approximated.

Insertion of a Percutaneous Screw Across a Longitudinal Sacral Fracture

Generally, the technique for insertion of a screw across a sacral fracture is similar to the method

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described for sacroiliac fixation.[38] The patient can be positioned in a fully prone, supine, or even a lateral decubitus position, although the crucial use of the image intensifier appears to be most readily achieved in the prone position. Imaging is most difficult in the lateral position. The target zone for the screw becomes the first sacral body, and to a lesser degree, the S-2 body. With the patient situated in a prone fashion, a guide wire is placed transversely across the middle of the S-1 body for an initial AP image (Figure 7.9). Then a transverse incision of about 3 cm in length is made at an equivalent point on the side of the injury that is about 6 cm posterior to the prominence of the greater trochanter. After spreading the incision down to the bone, with use of a small vascular clamp, the guide wire and drill sleeve assembly is introduced through the incision and advanced to bone. An AP image is taken to confirm that the second guide wire is coaxial with the first. The second guide wire is drilled into the lateral ilium for about 3 cm. An inlet view is taken to confirm that the guide wire is centrally disposed from anterior to posterior in the S-1 body. Also, the guide wire is oriented in a transverse manner so that it is not directed toward the front of the sacrum nor toward the neural canal. A supplementary outlet view is taken to ensure that the guide wire is oriented parallel to the top of the S-1 body and midway between the top and the S-1 foramen. If necessary, the guide wire is repositioned until these criteria are satisfied. In the presence of a pronounced osteophytic ridge along the anterior and superior border of the sacrum, the guide wire needs to be positioned a few millimeters more posteriorward in the S-1 body to ensure that the screw is within the bone. The guide wire is advanced so that it is embedded within the bone for about 90 mm. This distance is consistent with the screw threads of a long threaded screw being located within the S-1 body and between the ipsilateral and contralateral foramina.

After confirmatory AP, inlet, and outlet images are obtained, a supplementary direct lateral image is viewed. The position of the guide wire within the S-1 body is confirmed. If the fracture is an unstable one where displacement was documented prior to the closed or open reduction, a second iliosacral screw is inserted parallel to the first. The corresponding guide wire can be introduced into the S-1 or S-2 bodies. For a large male patient, the easier technique is the insertion of two screws into the first sacral body. In such a patient, frequently the S-1 body is large enough so that the two screws can be inserted with one in front of the other or with one superior to the other. In a small woman, the S-1 body may be too small to contain two sacral screws. Once the S-2 body is needed, the anatomical details of the sacrum need to be carefully reviewed. The S-2 body is substantially narrower than the S-1 body in the anteroposterior dimension. The anterior surface of the sacrum possesses a concavity so that the anterior surface of S-2 is considerably more posterior than the corresponding surface of S-1. In the inlet view, this curved configuration of the sacrum is radiographically obscured. Its crucial recognition is achieved by a scrutiny of the lateral image. For insertion of a second screw into S-1, the original incision can be used. For insertion of a sacral screw into S-2, a separate incision is made about 3 cm inferior to the first. The guide wire is advanced down to bone. An AP image is obtained to confirm that the second guide wire is parallel to the first and mid-axial with respect to the S-2 body. After the pin is advanced into the bone for about 3 cm, the AP, inlet, outlet, and direct lateral images are obtained. The guide wire is documented to be centered in the midportion of S-2 and to be parallel to the first guide wire. Then the guide wire is fully inserted to about 90 mm from the entry point in the lateral ilium. Once both guide wires are satisfactorily inserted, a depth gauge is applied over the guide wire. Then a 7.2-mm-long threaded cancellous screw of appropriate length is advanced over either guide pin and tightened.

Hazards and Associated Technical Details

For insertion of iliosacral screws into the mid-sacral region, subtle anatomical variations, possibly combined with conditions of less than optimal imaging, can lead to conditions of marked escalation in the risk of formidable complica-

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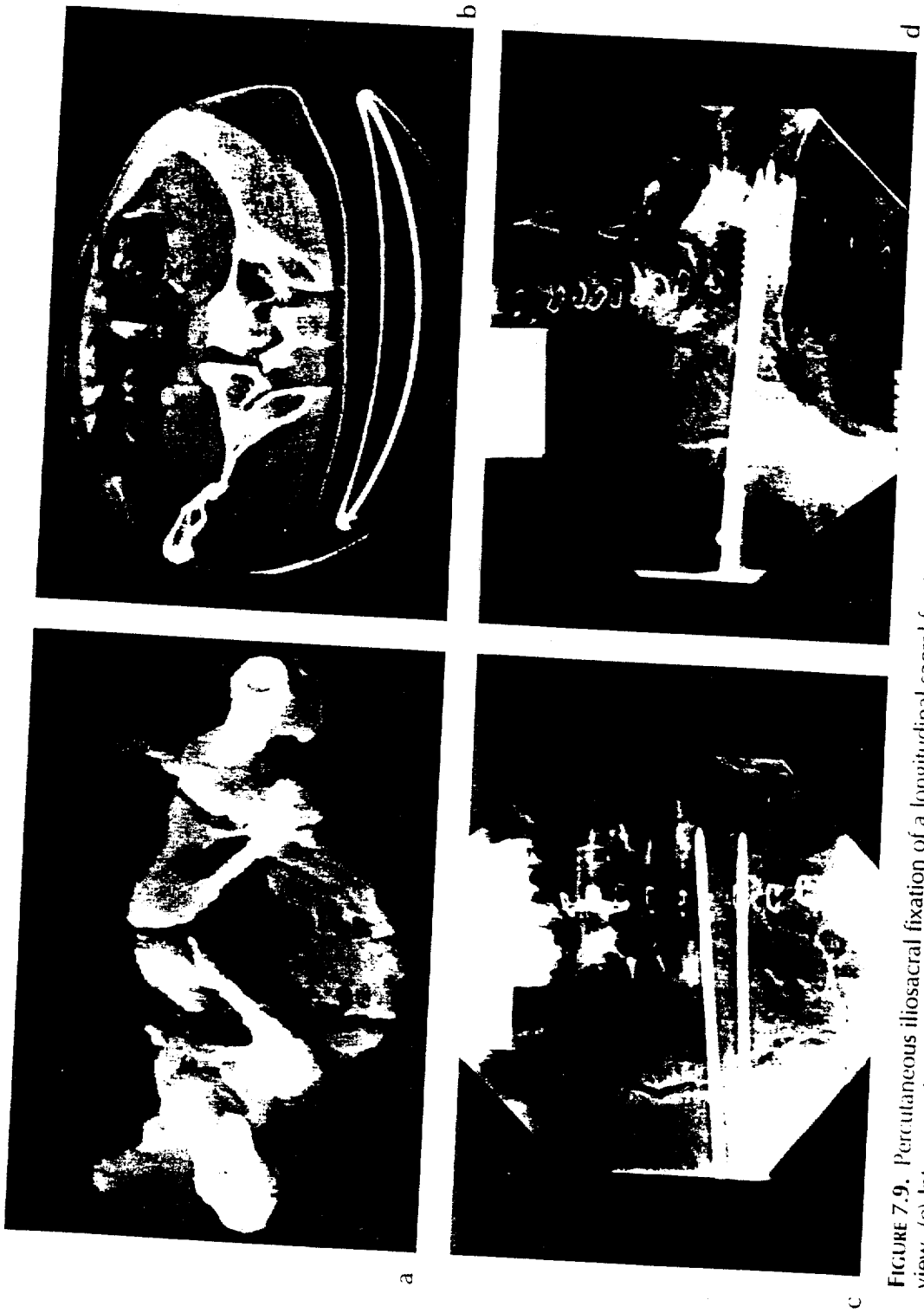

FIGURE 7.9. Percutaneous iliosacral fixation of a longitudinal sacral fracture. (a) Anterior outlet 3D CT view. (b) Transaxial CT view. (c) Intraoperative outlet view after guide wire insertion. (d) Intraoperative inlet view after screw insertion over guide wires.

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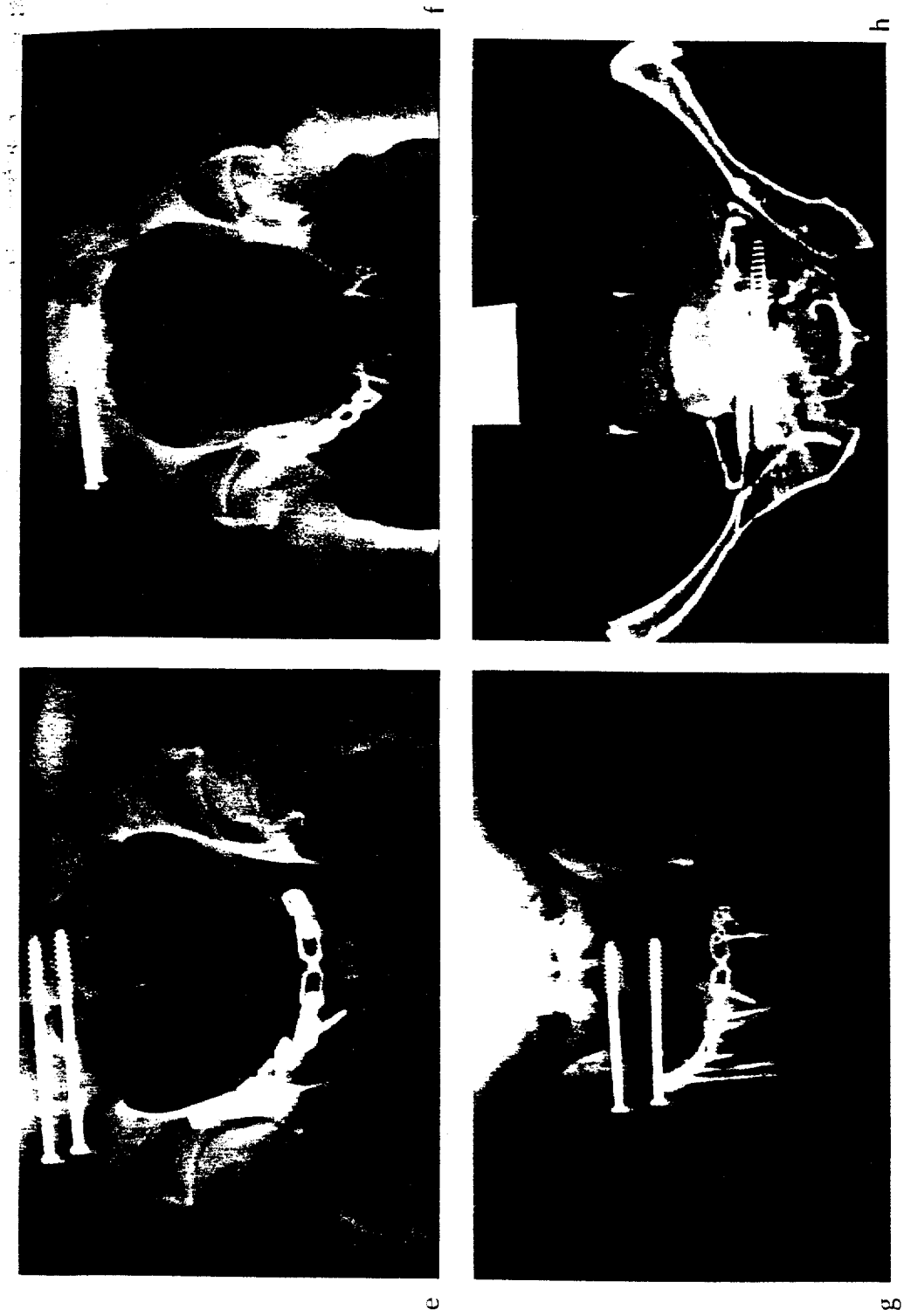

FIGURE 7.9 (e) Postoperative AP view. (f) Postoperative inlet view. (g) Postoperative outlet view. (h) Postoperative transaxial CT view.

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tions. The degree of lumbar lordosis and corresponding tilt of the sacrum influence the ideal orientation of the x-ray beam of the image intensifier that is appropriate for each patient.[38] The detailed features of the sacral anatomy vary considerably with further alterations afforded by degenerative changes. Transitional vertebra at the lumbosacral junction further complicate the imaging with the aberrant contours of the lumbarized S-1 or sacralized 1-5 vertebra. The sacral foramina possess a variable but oblique course through the bone. An appreciation of the apparent orientation of the foramina is further complicated by the degree of tilt of the sacrum. While a precursory inspection of the S-1 body might lead to an impression that a 30-mm cylindrical column of bone is available for the insertion of the two 7-mm screws, the actual space that is available is significantly compromised by the presence of the foramina. In many instances, a centrally placed screw will be surrounded by not more than 3 mm of bone at crucial sites such as the neighboring foramen. In the presence of morbid obesity, a paralytic ileus with dilated loops of bowel, contrast medium that is a residue of prior diagnostic studies, osteopenic bone, or a faulty image intensifier, inadequate resolution may necessitate abandonment of this method. The resources for open fixation of the posterior sacrum with a plate or with sacral bars should be available as an alternative. When a switch to open sacral fixation is necessary, the use of the prone position facilitates the altered surgical plan.

Bilateral Vertical Sacral Fractures

For the bilateral injury patterns, two therapeutic alternatives exist. Iliosacral screws can be introduced from either side of the sacrum (Figure 7.10). In this instance, the method is similar to that just described. In the center of the sacral body, however, four screws have to be positioned with an overlapping of screws that is thwarted by the limits of space. In a large male, this method is entirely suitable, although in a small female it may be impractical. The other option is to introduce two lengthy screws that traverse entirely across the posterior pelvic ring (Figure 7.11). Great accuracy in the orientation and location of the screws is essential. The imaging technique is similar to that described for the ipsilateral iliosacral screw. The transverse orientation is crucial for the entire 120 to 150 mm length of the screws. For fixation of a long threaded screw within bone, the screw thread is liable to cross the sacroiliac joint. This shortcoming appears to be relatively minor compared with the other practical considerations of these uncommon and challenging cases. The presenc of the screws has not been attributable to th complaint of late posterior pelvic pain.

Iliosacral Fixation in the Presence of Osteopenic Bone

A further technical complexity of sacral fixation with iliosacral screws arises when the quality of the bone is impaired by the presence of senile osteoporosis, steroid-induced osteopenia, or disuse atrophy related to the presence of a painful nonunion or nonunion malunion. Previously, i the screw thread did not anchor securely in the weakened bone, the fixation was unsatisfactory. In such a case, the use of supplementary methyl methacrylate to augment the strength of the pelvic bone stock is complicated by the limited thickness of the bone, the juxtaposition of nerve roots in adjacent foramina, and other neurovascular structures or viscera adjacent to the bone that are vulnerable to thermal damage imposed by solidifying extravasated cement. As an alternative, a novel method of securing two adjacent 7.2-mm cannulated screws with a 2.0-mm Dall-Miles cable has been devised.[39] The cable is passed through the cannula of one screw (Figure 7.12). Then it is advanced through a two-hole 3.5-mm plate that serves as a washer. Subsequently, the cable is retrograded through the cannula of the second iliosacral screw. The two free ends of the cable are passed through the holes of a second washer plate. A sleeve is applied to the ends of the cable prior to tightening the cable with the tightening instrument. Once the cable is taut, the sleeve is crimped and

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excessive cable is removed with the cable cutter. The screws are selected of a length whereby they extend across the posterior pelvic ring just to the surface of their threaded tips.

Acetabular Fixation with Cannulated Screws

The pattern of acetabular fracture dictates the type of surgical approach or approaches, the reduction strategy, and the preferred type of fixation. Historically, the posterior injury patterns including posterior wall, posterior column, posterior wall–posterior column, and posterior wall–transverse injuries have been visualized by resort to a Kocher-Langenbeck approach.[40] The anterior injury patterns include anterior wall, anterior column, anterior column or anterior wall–posterior hemitransverse, and most typical both-column fracture patterns. All of these injuries, including the last pattern which has a major constituent of posterior column that is contiguous with the quadrilateral surface, can be accurately reduced by resort to an ilioinguinal exposure. Admittedly, with delayed presentation, or in certain other complex injury patterns, a both-column injury may be best managed by the use of two approaches for anterior and posterior visualization, respectively. For transverse and T-type injury patterns, the optimal surgical approach varies depending upon certain subtle aspects of the injury. In some instances, the displacement is almost entirely posterior, where the anterior edge of the transverse fracture serves as a fulcrum. In this instance, a posterior approach may suffice. Examples would include many posterior wall–transverse fractures with minimal displacement of the transverse fracture itself, as well as some posterior T-type injuries. In other cases, the displacement is almost entirely anterior when an ilioinguinal approach may be preferred. When the entire transverse fracture is significantly displaced, then the anterior and posterior edges of the fracture need to be visualized for an accurate reduction. In this instance, an extended lateral approach, such as a triradiate or extended iliofemoral, may be necessary. For substantially displaced T-type fractures, another option is to use anterior and posterior approaches for the corresponding portions of the reduction.

For the reduction of an acetabular fracture, a broad spectrum of specialized reduction tools is available. Most of these forceps possess pointed tip jaws that are of various lengths and differing shapes. An alternative technique is to employ a Farboeuf forceps applied to screw heads after a screw is embedded in either principal fracture fragment.[40] This technique affords robust temporary fixation, although the time required for its application with insertion of the screws is somewhat longer than that required for the use of a tenaculum-type forceps. A special family of acetabular reduction forceps, identified as the king, queen, and prince tong, are particularly useful for spanning from the inside to the outside of the pelvis. The prince tong is a so-called eccentric forceps with jaws of differing lengths. It is perhaps the most satisfactory design for the reduction of the quadrilateral surface or of the posterior wall by resort to an ilioinguinal approach.

Most of the fractures are suitably immobilized by standard 3.5- or 4.5-mm cortical screws and highly flexible reconstruction plates. For immobilization of especially thin bone, such as the posterior and anterior wall, a hook or spring plate is fashioned from a 3.5-mm one-third tubular plate.[34] This method permits the fixation of thin sections of bone with a buttressing technique, whereby the screws are remote from the joint surface. For acetabular fixation, cannulated screws have a limited but valuable role for two special applications. Around the acetabulum, limited columns of bone, typically with a maximum diameter of 7 to 9 mm, provide the principal source of bone stock for fixation (Figure 7.4a). Log screw fixation of these columns by resort to conventional screws was popularized by Letournel.[21] With such a limited cross-sectional area for immobilization, the screw is highly vulnerable to extend beyond the surface of the bone prematurely, either to compromise fixation or to jeopardize adjacent soft tissues. With the use of a cannulated screw, the guide wire can be inserted initially for radiographic confirmation of appropriate position. Also, the guide wire ensures that the screw follows

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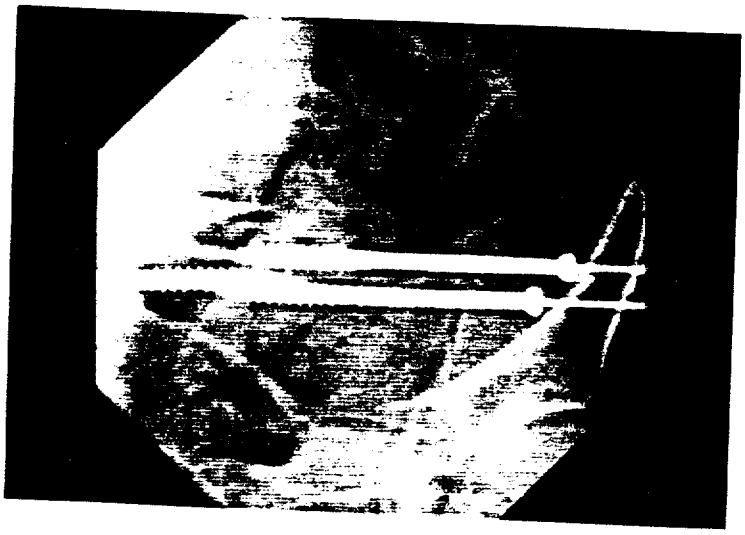

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FIGURE 7.10. Bilateral longitudinal fractures with percutaneous iliosacral screw insertion for a C-3 injury in a 43-year-old man. (a) Initial 3D CT. (b) Transaxial CT view of S-1 body. (c) Intraoperative outlet view.

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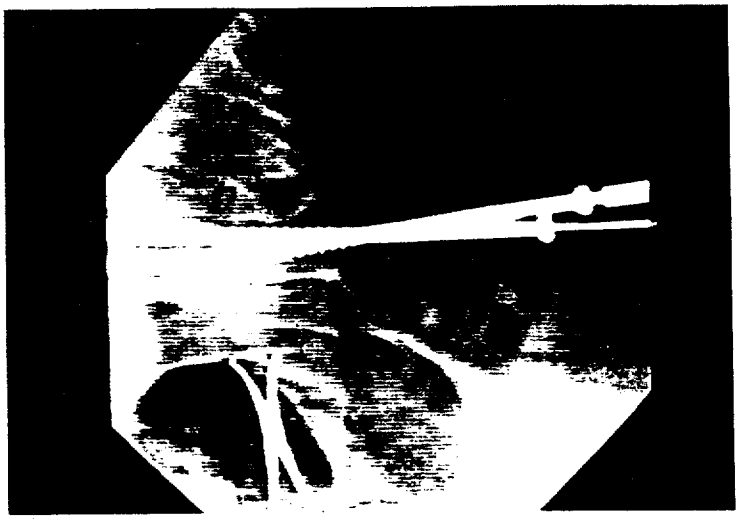

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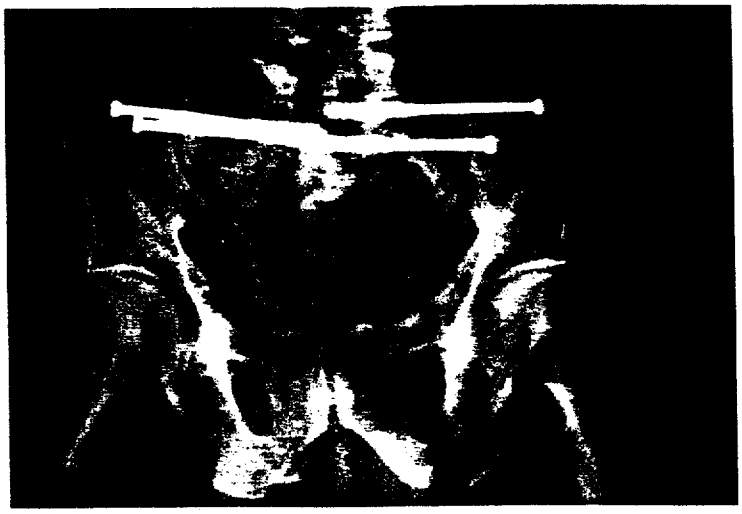

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FIGURE 7.10 (d) Intraoperative inlet view. (e) Postoperative AP view at one year. (f) Postoperative inlet view.

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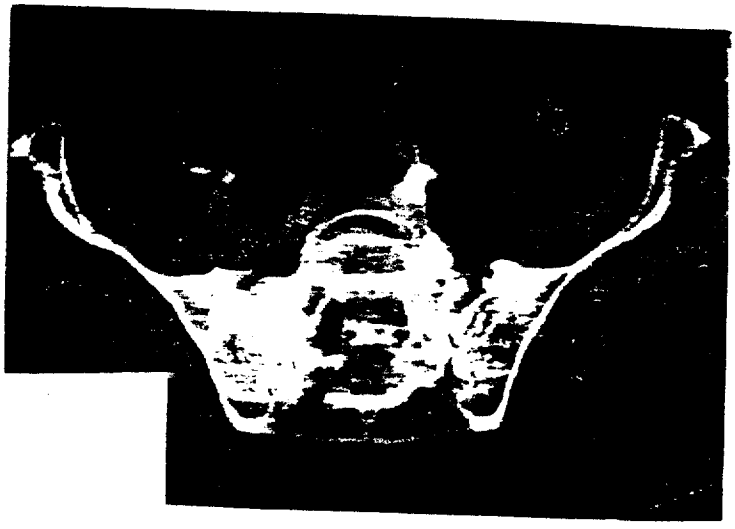

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FIGURE 7.11. Percutaneous iliosacral screw fixation and posterior plate fixation in a 72-year-old woman with bilateral sacral alar insufficiency fractures secondary to irradiation therapy for uterine carcinoma. The lengthy iliosacral screws were inserted through the left ilium. (a) Initial anterior 3D CT view. (b) Posterior 3D CT view. (c) Transaxial CT view of posterior pelvis.

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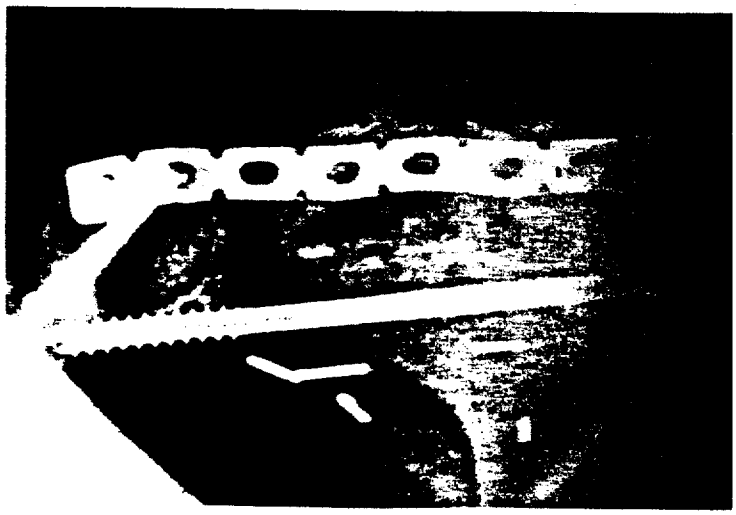

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FIGURE 7.11 (d) Postoperative AP view. (e) Intraoperative inlet view. (f) Intraoperative outlet view.

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FIGURE 7.12. Augmentation of cannulated iliosacral screws with 2.0-mm cable in a 63-year-old woman with posterior insufficiency sacroiliac disruptions secondary to extensive harvesting of bone graft. (a) Anterior 3D CT outlet view. (b) Inlet views. (c) Cable threaded through two cannulated screws. (d) Use of a two-hole plate as a washer.

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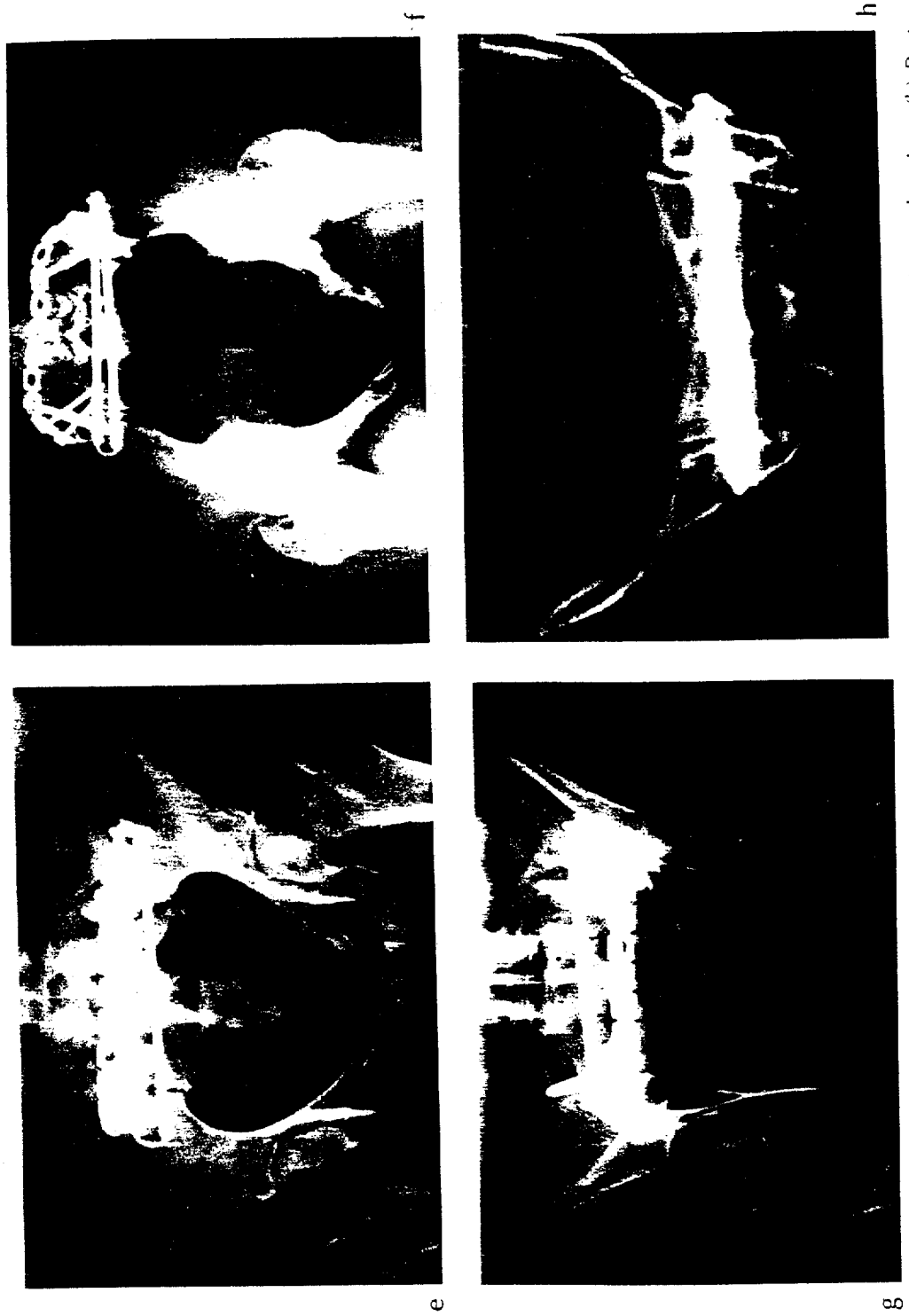

FIGURE 7.12 (e) Postoperative AP view one year later. (f) Postoperative inlet view. (g) Postoperative outlet view. (h) Postoperative transsacral CT views.

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FIGURE 7.13

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FIGURE 7.13. Percutaneous fixation of the anterior column in a 51-year-old man where a limited ilioinguinal approach to the medial eminence was undertaken to stabilize the quadrilateral surface. (a) Disarticulated 3D CT of acetabulum. (b) 3D CT of quadrilateral surface. (c) Superior 3D CT views. (d) CT view of dome. (e) Intraoperative iliac oblique view of plate on medial eminence. (f) Iliac oblique view highlighting percutaneous screws. (g) Postoperative anterior 3D CT view. (h) Postoperative 3D CT view of quadrilateral surface. (i) Postoperative obturator oblique view. (j) Postoperative disarticulated acetabular view. (k) Postoperative 3D CT with partial acetabular subtraction to confirm sagittal congruency. (l) Postoperative 3D CT with translucency of acetabulum to highlight fixation screws.

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exactly the same course as the guide wire. Alternatively, when a conventional screw is employed, occasionally, where the corresponding column of bone is curved, the initial drill bit may follow the course of the cancellous bone, although the larger screw may follow a different pathway, either to exit through the fracture or through relatively thin cortex. The other application of cannulated screws around the acetabulum is to achieve fixation with a minimally invasive or percutaneous technique. Certain acetabular fractures, especially of a transverse nature or as a pathologic variant, are minimally displaced but potentially unstable. Percutaneous screw fixation is a highly attractive method for immobilization. Other acetabular fractures merit approach by an acetabular exposure that is selected for the optimal visualization of the fracture and reduction. Nevertheless, that approach may be inappropriate for insertion of lag screws. In this instance, a cannulated lag screw may be inserted percutaneously, either as a principal or supplementary source of fixation (Figure 7.13). Perhaps the best example is fixation of the anterior column of a transverse fracture with a screw that courses through the superior gluteal ridge and along the superior pubic ramus, a so-called anterior column screw.

A 4.5-mm-diameter cannulated screw is preferred for acetabular fixation. The principal sites for insertion of such screws include the anterior, superior, and inferior spines, the posterior, inferior and superior spines, the superior gluteal ridge, and the posterior and anterior columns (Figure 7.4d). In practice, some of these sites of bony condensation are appropriate for either acetabular or pelvic ring fixation (Figure 7.14). Apart from the anterior column screw, the remaining sites for fixation are of sufficient size so that the 4.5-mm-diameter screw can be inserted with relative ease provided that image intensification with a high resolution is available. For the anterior column screw, a detailed scrutiny of the hemipelvis is necessary (Figure 7.15). The screw has to follow a pathway that is coaxial with the superior pubic ramus along its innermost aspect. The entry site is between 4 and 5 cm superior to the lateral acetabular margin. The screw enters the posterior aspect of the superior gluteal ridge. In some instances, the guide wire is best inserted prior to the reducti of the transverse fracture. In this way, the tip the guide wire exiting in the fracture surface permits a confirmation of the appropriate site of the guide wire through a column of about 40 mm in length. Once the fracture is reduced, then the column of bone becomes 80 to 100 mm in length, whereby the assessment of the target zone is much more difficult. During the insertion of the guide wire, the image intensification confirms the appropriate pathway by viewing the AP, inlet, and Judet views. The inlet view permits a confirmation that the screw follows the course of the pelvic brim. The obturator oblique view permits a documentation that the screw i consistent with the position of the acetabular roof.

For a both-column fracture with the typical high anterior fracture fragment, screws inserted into the anterior aspect of the anterosuperior spine and through the anteroinferior spine permit effective fixation with little prominence of the fixation device (Figure 7.4d). The former screw passes immediately along the course of the iliac crest through the corresponding thickened ridge of bone. The latter screw is inserted slightly to the lateral aspect of the most prominent tip of the anterosuperior spine. The screw continues parallel to the course of the sacroiliac joint as documented on the obturator oblique view. A supplementary iliac oblique view permits documentation that the screw is directed superior to the roof of the greater sciatic notch into the so-called greater sciatic buttress. The use of this screw is also appropriate for a high transverse fracture. In this case, however, the screw is directed more inferiorly toward the greater sciatic notch. Here the guide wire is assessed on the iliac oblique view to ensure that it does not extend beyond the confines of the posterior column where impalement of the sciatic nerve would become a possibility. Again, the obturator oblique view permits documentation that the screw follows the course of the roof of the acetabulum.

For a both-column fracture complicated by a large posterior wall fracture fragment, initially most of the injury is reduced and stabilized by resort to an ilioinguinal approach. For immobilization of the posterior wall, and potentially the

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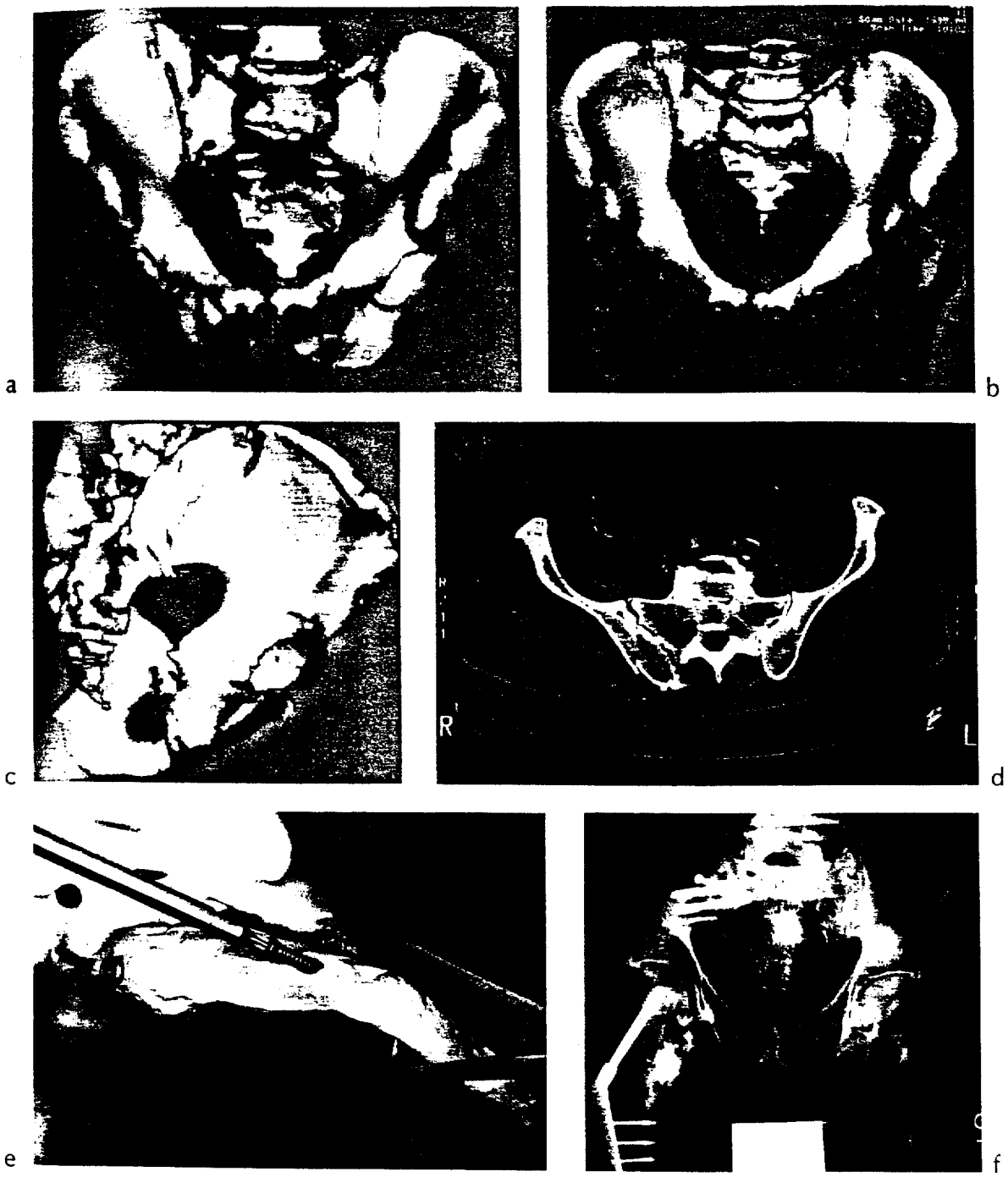

FIGURE 7.14. Example of posterior iliac fixation with percutaneous screws inserted into postero-superior and -inferior spine for an insufficiency fracture in a 78-year-old man. (a) 3D CT anterior view. (b) 3D CT inlet view. (c) 3D CT external iliac view. (d) Transaxial CT view. (e) Direction of screws inserted through the posterior spines. (f) Postoperative AP view with two posterior iliac screws and one iliosacral screw.

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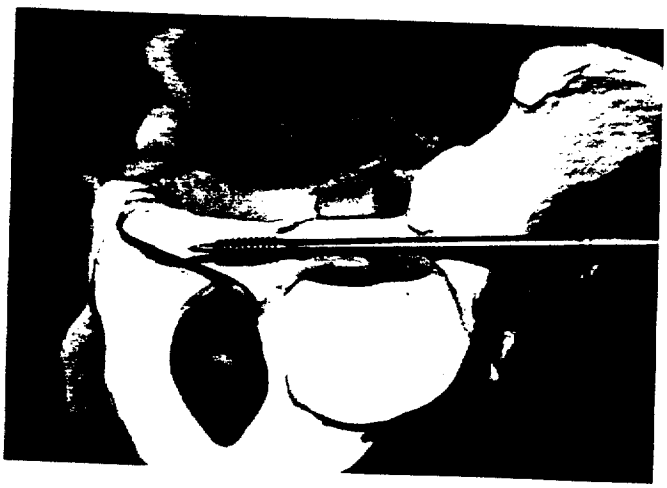

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FIGURE 7.15. Insertion of an anterior column lag screw including clinical case with nonunion of anterior column and sacral ala in a 39-year-old man. (a) Position of cannulated screw. (b) Corresponding intraoperative obturator oblique view with guide wire. (c) Subsequent insertion of 3.5-mm cannulated screw. (d) Preoperative AP view with nonunions of the sacrum and anterior column.

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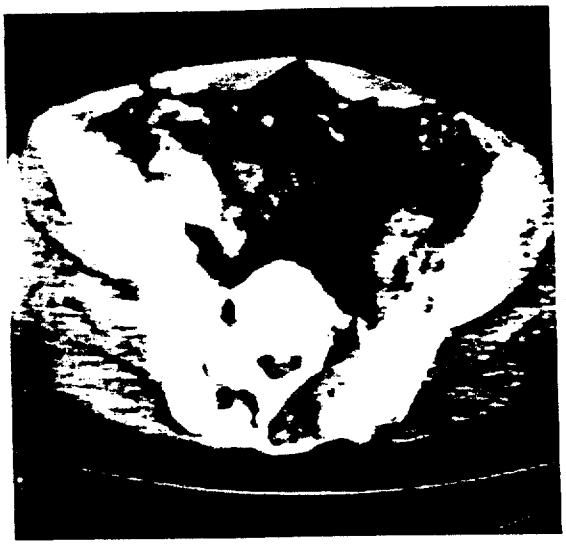

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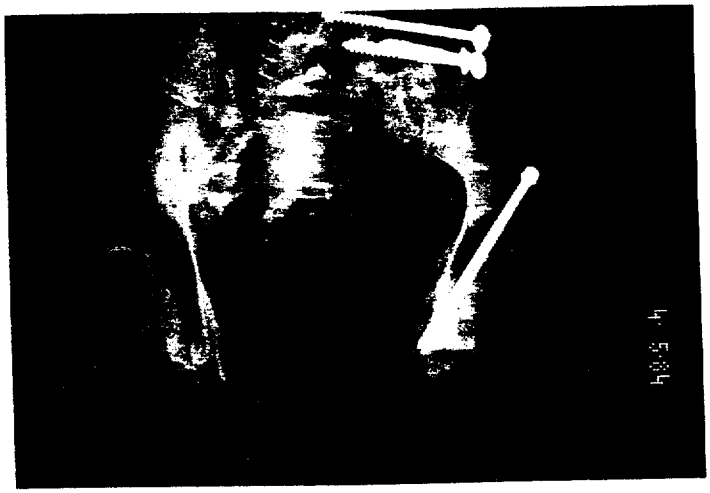

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FIGURE 7.15 (e) Preoperative obturator oblique view. (f) Preoperative CT view. (g) Postoperative AP view. (h) Postoperative inlet view.

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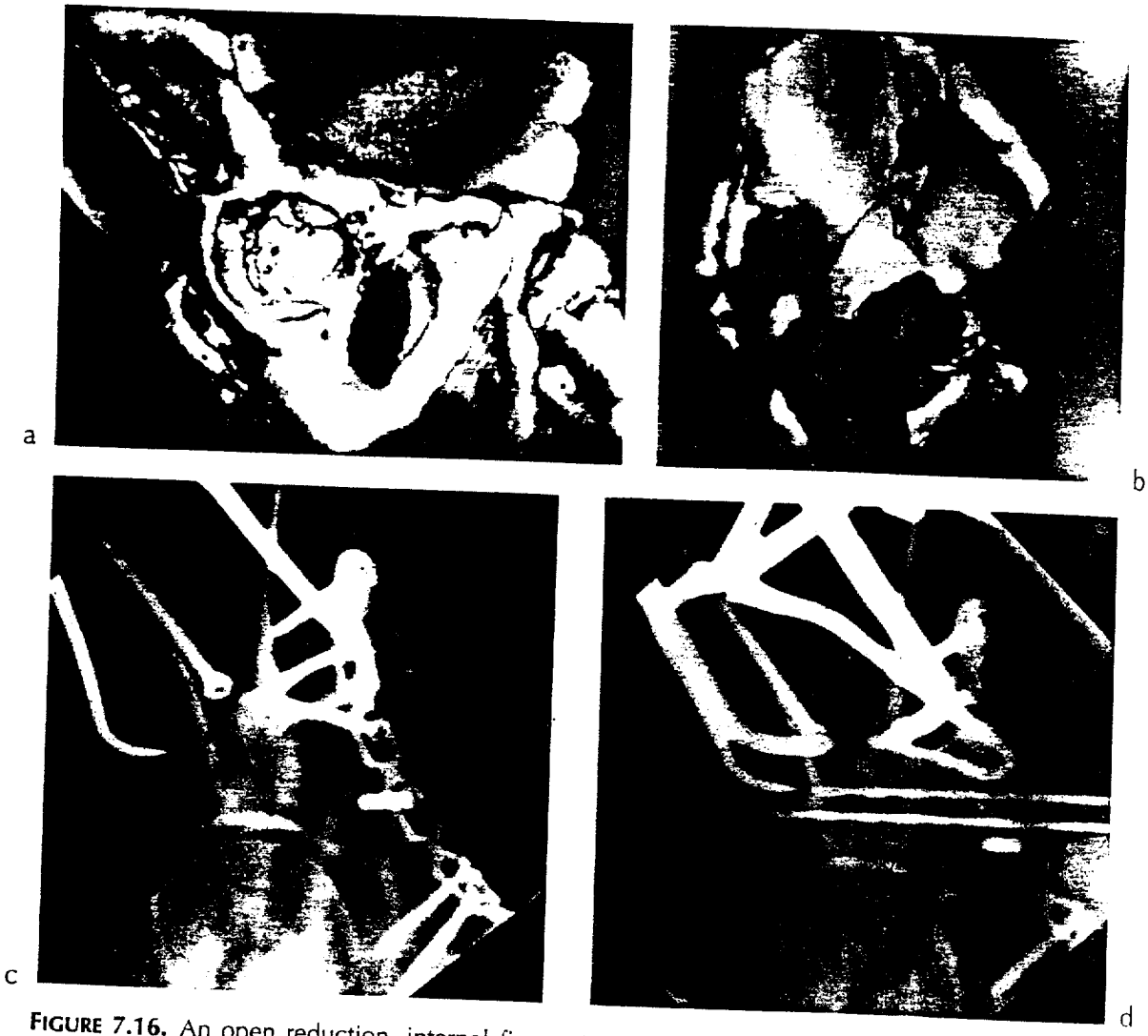

FIGURE 7.16. An open reduction, internal fixation of a both-column posterior wall fracture by resort to an ilioinguinal incision. After an open reduction of the anterior and posterior columns, the posterior wall fragment is immobilized with a pointed forcep and cannulated screws are inserted from the pelvic rim into the fragment. (a) Disarticulated 3D CT acetabular view. (b) External iliac 3D CT view. (c) Intraoperative obturator oblique view with reduction of posterior wall fragment. (d) Intraoperative obturator view with insertion of guide wires for cannulated screws.

associated posterior column, two methods are feasible. A second Kocher-Langenbeck incision can be used for the posterior exposure. Certainly this is the preferred method for a fracture of belated presentation.[41] Another possibility is to use solely an ilioinguinal approach (Figure 7.16). After fixation of the anterior and posterior columns, the posterior wall is immobilized. A limited pathway is developed between the anterior superior and inferior spines that follows the outer table of the pelvis to the posterior wall. The longer jaw of the prince tong forceps is passed along the outside of the acetabulum to impinge upon the posterior wall fragment. Under image intensification, the wall fragment is reduced. Immobilization can be achieved with

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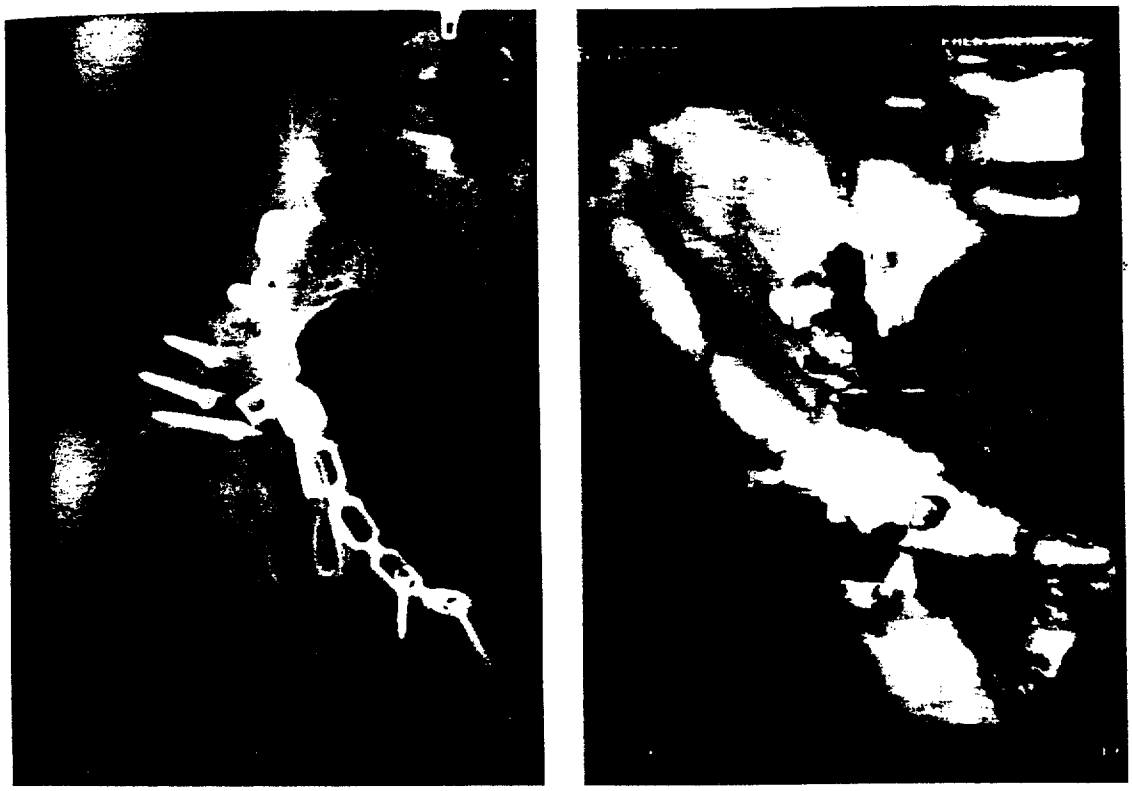

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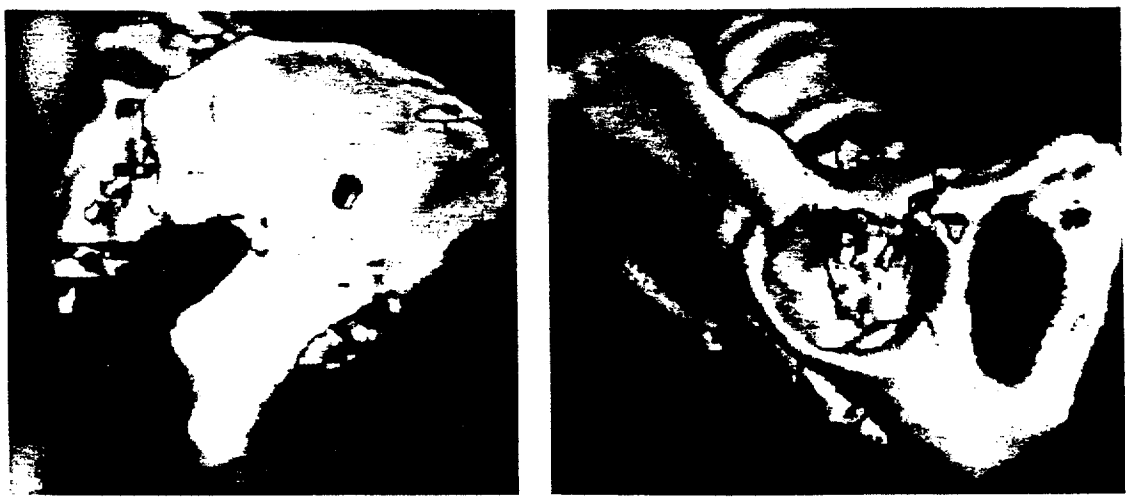

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FIGURE 7.16 (e) Postoperative AP view. (f) Postoperative anterior 3D-CT view. (g) Postoperative iliac 3D-CT view. (h) Postoperative disarticulated view.

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FIGURE 7.16 (*continued*) (i) Postoperative inner view. (j) Postoperative transaxial view. (k) Postoperative sagittal view. (l) Postoperative coronal view.

two of the 4.5-mm cannulated screws that are inserted near the pelvic brim and directed toward the posterior wall. This retrograde fixation eliminates the need for the second surgical approach. The entry site is slightly medial and posterior to the prominence of the medial eminence.

Another site for immobilization of the anterior column is insertion of the cannulated screw medial to the pubic tubercle and directed along

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the superior pubic ramus.[42] The screw is inserted between 2 and 3 cm from the symphysis pubis. The pathway of the guide wire is primarily followed in the obturator oblique view and the inlet view. Meticulous documentation of the pathway of the screw is necessary to ensure that the screw does not penetrate the hip joint. In essence, this method, which was popularized by Routt et al.,[43] represents a retrograde insertion of an anterior column lag screw.

Intraoperative Imaging

Once the fixation has been inserted, careful imaging of the hemipelvis is needed to ensure that the reduction and fixation are satisfactory. The reduction is assessed for its accuracy with respect to the amount of persistent displacement and the restoration of congruity of the joint. Even under ideal intraoperative conditions, it is unlikely that the accuracy can be assessed with a resolution of better than 2 to 4 mm. Restoration and documentation of congruency of the acetabular surface with respect to the femoral head is critical. Multiplanar imaging is necessary with respect to the assessment of congruency and residual displacement. The presence of fixation plates may greatly hamper the quality of the imaging. The other critical documentation is the absence of a screw from the hip joint. Such confirmation can be surprisingly difficult. It is not unusual for meticulous intraoperative imaging to be undertaken with an apparent acceptable appearance when a postoperative CT scan confirms the penetration of the hip joint by a screw. In addition to the various multiplanar views, a supplementary image is taken in a plane that is coaxial with the course of a high-risk screw. Once the screw has been inserted, a screwdriver for use in a power tool is inserted into the corresponding recess of the screw head. The x-ray beam is aligned so that it is coaxial with the course of the screw and the screwdriver. The shaft of the screwdriver provides an aligning guide to assist in the adjustment of the x-ray tube. The highest risk is the anterior acetabulum where a plate is positioned along the true pelvic brim and an associated screw is directed parallel to the quadrilateral surface.

Postoperative Imaging Following Surgery

After completion of an acetabular reconstruction, a complete standard radiographic series and a CT scan are strongly recommended. As a bare minimum, postoperative AP, inlet, and outlet views are necessary, while supplementary inlet and outlet views are recommended. Nevertheless, a standard CT scan with 2.0- to 3.0-mm cuts across the acetabulum greatly assists in an assessment of accuracy of the reduction. The author prefers to obtain a supplementary postoperative 3D CT scan with supplementary images that disarticulate the femoral head (Figures 7.5, 7.13, and 7.16). Typically, even in the presence of a very accurate reduction as assessed by conventional radiographs, an associated CT scan and 3D CT scan will confirm the presence of imperfections in the reduction that otherwise would be unrecognized. If the accuracy of the reduction is a major aspect of prognostication for prolonged function of the hip, the CT affords the most critical assessment of the reduction with sobering recognition of postoperative malreduction. A surgeon is liable to become much more critical of his reduction strategy on subsequent acetabular reconstructions.

The Use of Computed Tomographic Guidance For the Insertion of Cannulated Screws

Insertion of Iliosacral Screws to Immobilize the Sacroiliac Joint and Sacral Fractures

Prior application of the image intensifier to facilitate percutaneous insertion of cannulated screws for pelvic and acetabular fixation has been compromised by the limited resolution that is attainable with this method. Under ideal conditions, the resolution suffices to provide efficacious guidance for the procedure. In the presence of a paralytic ileus, morbid obesity, or osteopenic bone, the use of the image intensifier

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may become difficult or unrealistic. Recently, several attempts have been made to employ CT guidance for insertion of the percutaneous pelvic screws.[44,45] The method has been employed in the radiographic suite where typically epidural anesthesia is used. The method is particularly suitable for unstable but well-aligned fractures that are immobilized in situ. The technique can be performed with the patient situated in a supine or lateral position. A scout CT scan is obtained to permit the determination of the ideal center axis for the screw. The entry point thereby is predetermined, along with the angulation of the screw with respect to the horizontal axis. The computer assists in determination of the distance of the cutaneous surface to the outer cortex of bone and the optimal length of the screw. A small incision is made for insertion of a guide wire with drill sleeves. After determination of depth, a cannulated drill is employed prior to insertion of the 6.5- or 7.0-mm cannulated screw. Ebraheim et al.[44] employed the method for insertion of iliosacral screws. Duwelius et al.[45] also described the insertion of posterior iliac screws that extended transversely from one posterior superior spine to the other. The latter method was employed for immobilization of sacral fractures. Clinical experience has documented the superb accuracy of the CT guidance. The authors have acknowledged the potential compromise to the sterile field that is consistent with completion of such a procedure in the radiographic suite. Where the pelvic fracture is displaced, some supplementary procedure may be needed to achieve an accurate reduction. The ancillary procedure might include an open reduction of the symphysis or insertion of an external fixation pin into the anterior superior spine, or the application of supplementary skeletal traction. Undoubtedly, with the difficulties to achieve an accurate reduction, a potential shortcoming of the method would be acceptance of a malaligned fracture where inadequate reduction techniques were utilized. In a review of the clinical cases submitted for publication by Ebraheim et al. and Duwelius et al., a notable feature of most of the cases is a marked malreduction that at least for many surgeons would be considered unsatisfactory. The target zone for safe insertion of iliosacral screws is markedly reduced in the presence of a malaligned [illegible]ure. The risks for impalement, especially of a [illegible]acral nerve root, thereby are markedly increased. Clearly, implementation of the method would be greatly enhanced by the availability of a CT scanner in the operating room.

More recently, Kahler[46] has reported the application of CT guidance for percutaneous fixation of acetabular fractures. The methodology was very similar to that described for pelvic ring fixation. To date, the principal problem has been attainment of a satisfactory closed reduction of the fracture. Where an acetabular fracture is truly undisplaced, probably the [illegible]n-jury is significantly stable so that the nee[illegible]or fixation is relatively limited. Once the fracture is displaced, the restoration of an anatomical reduction is greatly hampered by the percutaneous methodology and the presence of the CT scanner gantry. Kahler has devised a radiolucent lateral traction frame as a means to achieve an accurate reduction in this constraining environment. While a reported pilot study provides encouraging results, further clinical documentation will be needed to validate the assets of the method.

Clinical Results with Percutaneous Cannulated Screw Fixation of the Pelvic Ring

Recently, Routt et al.,[47] reported the results of iliosacral screw fixation in 66 patients managed for posterior pelvic ring disruptions. For this group, 100 iliosacral screws were employed. Of the 34 male and 32 female patients, the range of age was from 11 to 33 years. The source of the injury was a motor vehicle accident in 36 patients, motorcycle trauma in 12 patients, pedestrian insults in 8 cases, with 5 crush injuries and 5 cases of a fall from a great height. The sacroiliac joint was disrupted in 59 patients, and a sacral fracture was documented in 31 patients, and combined or bilateral injury patterns were present in 24 patients. While all of the screws were placed percutaneously, 96 were inserted into the first sacral body and 4 into the second sacral body. For the reduction of the pelvic ring, an open anterior approach, the fixa-

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tion of an associated acetabular fracture, the application of longitudinal skeletal traction, the insertion of an iliac crest pin or screw, or a femoral distractor was employed. Intraoperative imaging was hampered in 18 patients by the presence of significant flatus or intraabdominal contrast media related to prior imaging studies. In nine other patients, morbid obesity complicated the imaging and screw placement. Also, the standard instruments for cannulated screw insertion were of insufficient length for routine screw placement in all nine cases. Ten of the patients possessed features of sacral dysplasia that altered the typical site for optimal screw placement. In two of these cases, hazardous insertion of the screws ensued. One of the patients sustained an L-5 neuropraxia related to problematic screw placement. In another patient, a screw exited from the contralateral ala. There were no infections, wound problems, and no cases of significant blood loss. In two patients, the screws failed at approximately 6 months following surgery. Both of the cases were notable for highly unstable sacral fractures. One of the patients progressed to a symptomatic nonunion so that a supplementary bone graft was necessary. Two other patients progressed to failure of fixation. These cases were complicated by craniocerebral trauma with spasticity and combativeness.

In a separate report by Keating,[48] 40 unstable pelvic fractures were managed with iliosacral screw fixation. Twenty-nine of the cases were highly unstable injury patterns. In the retrospective analysis, six of the screws were misplaced, typically with an unacceptable anterior position. The initial reduction was judged to be satisfactory in 33 patients, while ultimately 19 patients (48%) developed a malunion, irrespective of the type of the anterior fixation. At the time of the final assessment of 1 to 4 years after the time of the injury, 33 patients complained of low back or posterior pelvic pain, of which three cases had severe and disabling symptoms. Half of the patients returned to their original employment, although 33% progressed to long-term disability. Sixty-eight percent of the cases failed to return to a former level of recreational activity. The authors felt that the results of iliosacral fixation for highly unstable pelvic ring disruptions were consistent with low mortality and morbidity but with disappointing long-term anatomical and functional results.

In a separate analysis, Routt et al.[43] reported the results of 24 patients in whom 28 retrograde superior pubic ramus screws were inserted under biplane image intensification. Fifteen of the screws were inserted percutaneously in 15 patients following a closed manipulation of the fracture. In nine other patients, 13 screws were inserted as part of an open reduction of the ramus fracture by resort to a Pfannenstiel exposure. Four of the patients were managed with bilateral screws for bilateral ramus fractures. Of these cases, 11 screws were inserted so that they passed cephalad to the acetabulum and exited from the lateral ilium. None of these screws violated the acetabulum. There were no nonunions or infections, while all of the fractures healed uneventfully. There was no screw breakage evident in any of these cases. In five of the patients, however, errant screw placement was documented only in postoperative plain radiographs. or in two cases, a postoperative CT scan. In all of these cases, intraoperative image intensification had been employed and was apparently satisfactory. This technical shortcoming highlights the difficulties in the application of the image intensifier in the operating room, even in highly experienced hands.

Author's Philosophy

Percutaneous fixation and the use of cannulated screws for immobilization of the pelvic ring and acetabulum remain a highly attractive method that is still in a preliminary stage of clinical application. The attributes include minimal surgical invasiveness, combined with the potential for rapid and stable fixation. This method is especially suitable for minimally displaced but potentially highly unstable fractures. The technique has a potential for application during the early resuscitative phase as an alternative to external pelvic fixation. Nevertheless, the technique has considerable potential for surgical hazards, and it utterly depends upon the availability of high-quality image intensification. Perhaps the biggest shortcoming to date has been

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the difficulty to achieve adequate closed or open reductions, so that the method was not feasible. Unless an accurate pelvic or acetabular reduction can be achieved, the fixation of a malaligned fracture with percutaneous screws is contraindicated. With respect to the pelvic ring, an open reduction or the application of a fixation pin in the iliac crest or other indirect method may well suffice to obtain an accurate reduction of the posterior pelvic injury. With respect to acetabular fractures, currently the potential for closed methods to achieve an accurate reduction is highly limited. As an exception, the pathologic acetabular fractures of the elderly with minimal displacement are particularly suitable for fixation with cannulated screws. In the future, CT guidance may become a viable alternative to the image intensifier. Undoubtedly, the availability of a high-speed CT scanner in the operating room would immeasurably increase the role for this type of guidance for percutaneous screw insertion.

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15
Ankle Arthrodesis

Arthur K. Walling and Brian J. Padrta

While joint replacement has flourished in the majority of joints, its disappointing results in the ankle have contributed to the continued popularity of arthrodesis as a dependable and acceptable method of treatment for disorders of the ankle. Arthrodesis of the ankle has become the most frequently performed fusion procedure of major joints. It is most commonly performed for traumatic arthritis, but it is also an effective and reliable treatment for patients with inflammatory arthridities, instability, or failed arthroplasty (Figures 15.1 and 15.2).

External Verses Internal Fixation

Charnley[1] initially popularized the use of external fixation to provide compression at the site of fusion. More recent fixateurs, such as the Calandruccio frame, have used triangular configurations in an attempt to improve stability.[2,3] Despite these improvements, biomechanical studies comparing external fixation to internal fixation show superior stability with internal fixation.[4] Moeckel et al.[5] compared the clinical results between internal and external fixation methods for arthrodesis in a group of 68 ankles. Those ankles treated with internal fixation had a union rate of 95% compared with 78% for those treated with external fixation. External fixation is also associated with higher incidences of infection (secondary to pin tracts) and overall complication rates.[6] From the patient viewpoint, external fixation is bulky, requires daily pin care, and thus remains unpopular. Because of these factors, use of external fixation is best reserved for septic situations, and internal fixation has become the most widely accepted method achieving stability and compression at fusion site.

Methods of obtaining compression arthrodesis with internal fixation are varied. Studies comparing the use of plates vs. screws for obtaining internal fixation have shown that double-T plating does provide a more rigid construct, but has the disadvantage of requiring more soft tissue stripping and may jeopardize vascularity to the talus and tibia.[7] We also feel that it is more difficult to achieve compression across the fusion site when using only plate fixation. Because of this, we continue to prefer the use of transarticular cancellous screws to obtain compression arthrodesis.

Multiple configurations for screw placement exist, and debate regarding the number of screws needed for fixation and their positioning continues. Most authors use at least two screws to obtain fixation and prefer proximal to distal positioning.[8] Mann et al.[9] describes a technique from distal to proximal with the insertion point beginning in the lateral talus and proceeding upward across the ankle joint into the tibia. Friedman et al.[10] tested paired cadaver ankles and found that two 6.5-mm crossed cancellous screws placed from proximal to distal were superior to parallel screws in resisting torsional stress. A University of Washington study felt strongly that three screws are necessary for fixation and that the crucial screw is one placed from the posterior malleolus of the tibia into the neck and head of the talus.[11] Biomechanically, the three-screw configuration is more rigid but may not affect clinical outcome when compared with the use of two screws in uncomplicated cases[12] (Figure 15.3).

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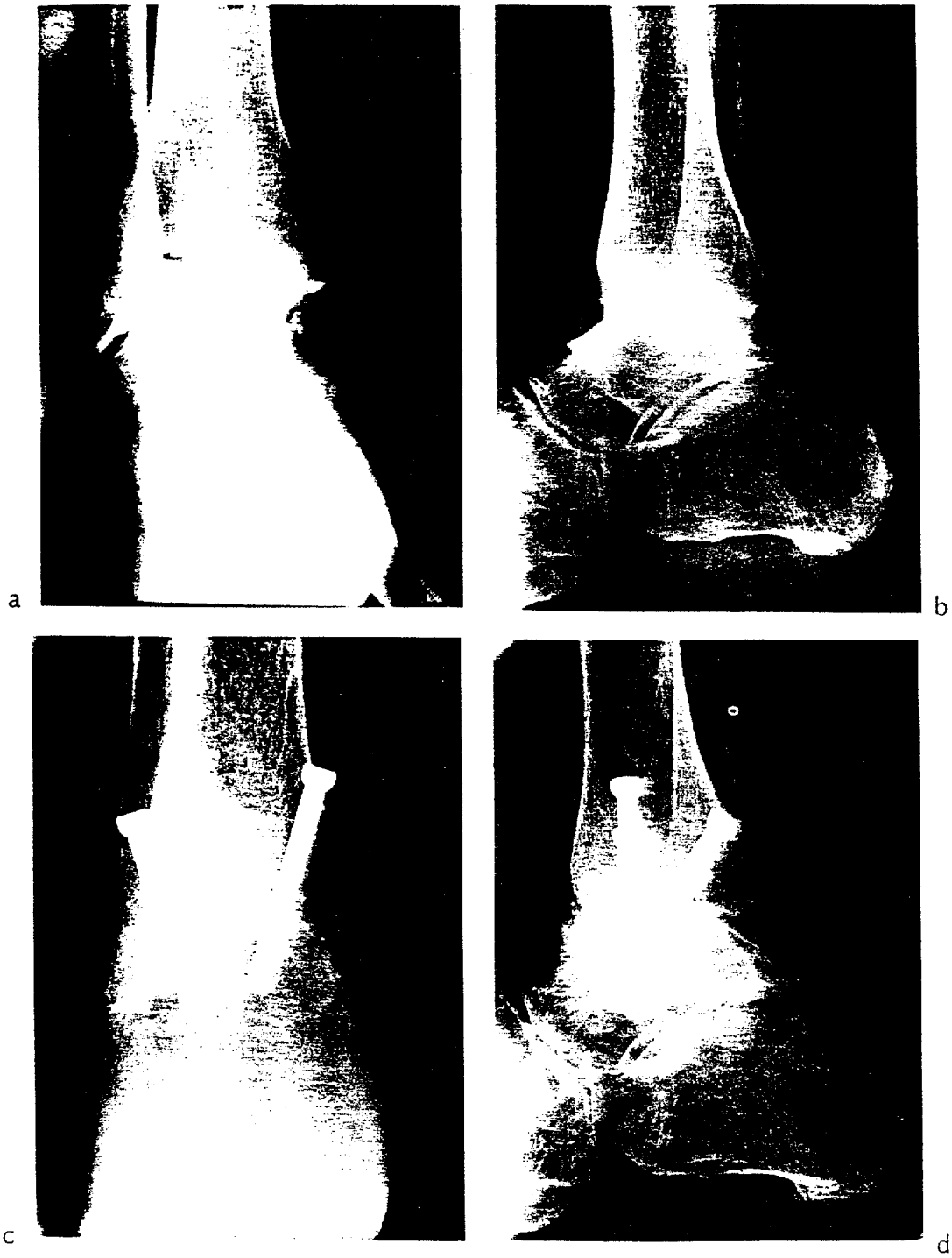

FIGURE 15.1. (a and b) Preoperative AP and lateral radiographs of a 79-year-old man with progressive pain and crepitance of the right ankle. (c and d) Postoperative AP and lateral radiographs illustrating the correct positioning of the posterior-anterior screw when utilizing the three-screw fusion technique.

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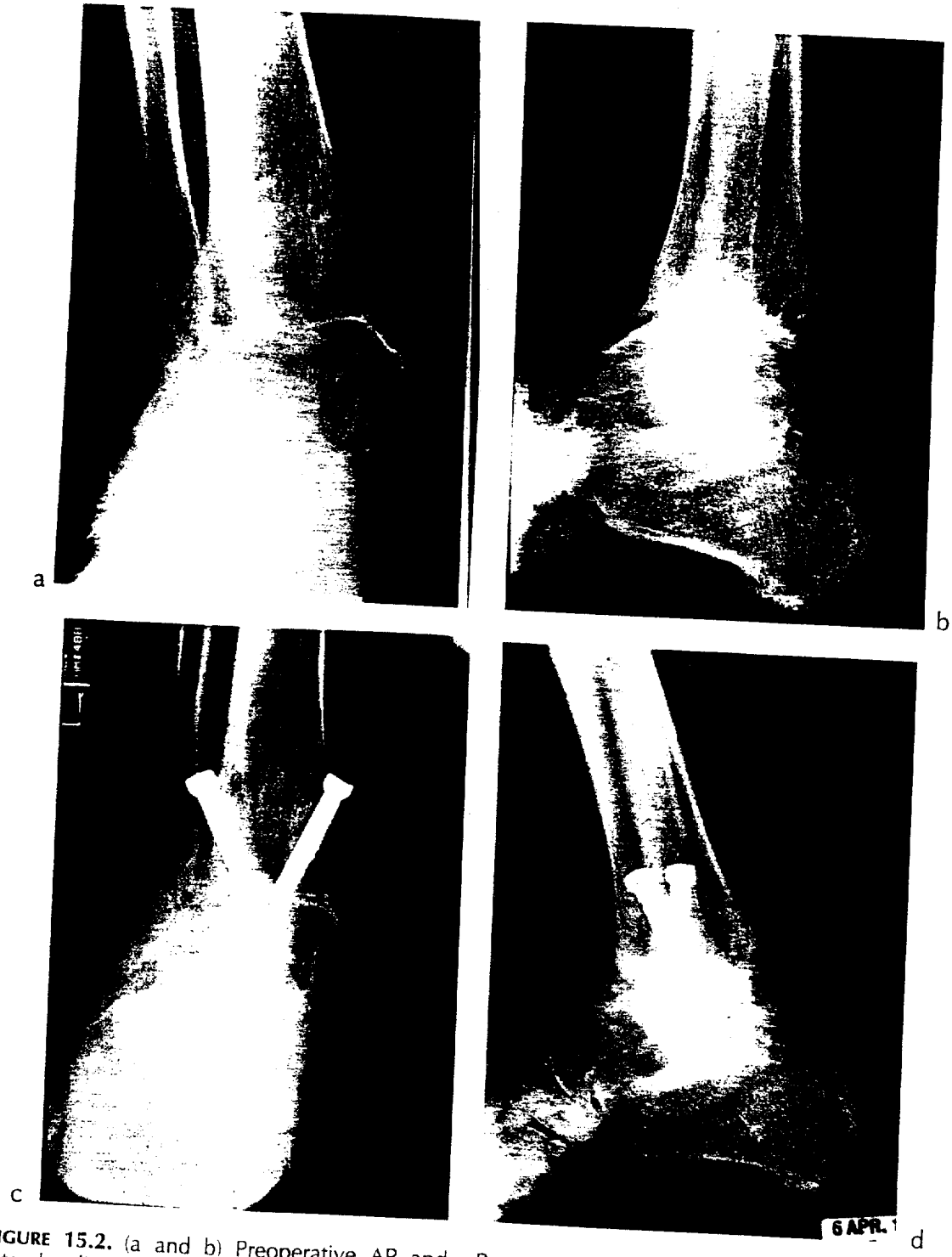

FIGURE 15.2. (a and b) Preoperative AP and lateral radiographs demonstrate lateral articular loss secondary to progressive talar tilt in a patient with valgus malalignment. (c and d) Postoperative radiographs of healed fusion, which show correction of the malalignment utilizing the two-screw technique.

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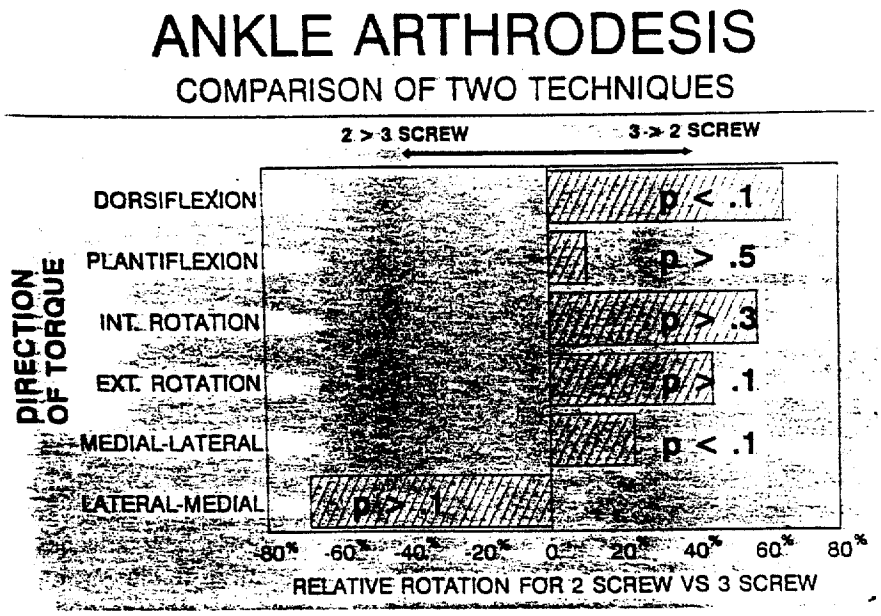

FIGURE 15.3. Biomechanical testing of two screws (medial/lateral) vs. three screws (posteroanterior, medial, and lateral) showed greater resistance to rotation in five of six planes with the three-screw technique. This was not statistically significant and may be clinically irrelevant if postoperative immobilization is employed.

Operative Technique

Multiple techniques and surgical approaches have been described to achieve arthrodesis. We prefer an anterior approach in most instances and utilize a lateral approach when it is necessary to remove internal fixation or when significant anterior displacement of the talus and foot in the ankle mortise exists, as can occur following pilon fractures. When determining which technique to utilize the surgeon must consider the underlying disorder, degree of deformity, bone stock, and patient demands.

The goal of the arthrodesis is to position the ankle in a neutral flexion-extension position with approximately 5° of valgus. It is equally important to position the foot along the weight-bearing line of the tibia, or slightly posterior, so that the overall length of the foot is decreased in relationship to the tibia. This shortens the lever arm and is believed to improve gait dynamics postfusion. External rotation should be approximately 5° to 10° and is best judged by comparison to the opposite ankle. The emphasis should be on rigid internal fixation, minimal bony resection, and meticulous soft tissue handling.

Cannulated cancellous screws are a practical method of achieving rigid internal fixation with compression across the arthrodesis site.[12] Placement of the guide pins under direct vision enables accurate assessment of eventual screw positions. The use of fluoroscopy further confirms screw placement and length. The pins themselves assist in maintaining the arthrodesis in the correct position prior to screw placement. In addition, the ability to place the screws percutaneously leaves soft tissue intact, thereby preserving vascularity. Cannulated screws are invaluable if using an arthroscopic technique for fusion.

Advantages of Cannulated Screws

1. The ankle is readily accessible to fluoroscopic placement of guide pins.
2. The guide pins can provisionally hold the arthrodesis in position and readily be repositioned if necessary prior to definitive screw placement.

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3. Guide pins can be used retrograde from within the articular surface of the tibia through the tibial metaphysis, then later antegrade, after foot provisional positioning, into the talus.
4. Guide pins can be used percutaneously with the aid of fluoroscopy and arthroscopy to do a percutaneous arthrodesis.
5. The use of provisional guide pin placement minimizes soft tissue dissection in the ankle where very little soft tissue covers much of the bony structure.

Authors' Preferred Equipment

Large cannulated screws: Partially threaded 6.5-mm titanium screws. *Guide pin*, 3.2 mm.

Small cannulated screws: Partially threaded 4.5-mm stainless steel screws. *Guide pin*, 2.0 mm.

Anterior Approach

The patient is positioned supine on a fluoroscopic-compatible operating room table with a "bump" under the ipsilateral hip. The iliac crest is prepared for bone graft harvest. A tourniquet is used throughout the procedure to control bleeding and enhance visualization. The anterior approach utilizes the interval between the tibialis anterior and extensor hallucis longus tendons. The neurovascular bundle is carefully identified and retracted laterally. The periosteum of the tibia and capsule of the ankle joint are incised in line with the skin incision. The full extent of the ankle joint can then be exposed by subperiosteal and subcapsular dissection. The articular surfaces of the ankle joint are denuded of cartilage with an osteotome, being careful to avoid excessive bony resection. A lamina spreader, pituitary rongeur, and powered osteotome are very helpful in ensuring complete cartilage excision from all surfaces. In addition, the tibiotalar surfaces and the medial-lateral gutters should be fully denuded. Any varus-valgus malalignment is corrected prior to fixation (Figure 15.2). Once the desired position for arthrodesis has been obtained, the placement of the screws can commence.

If utilizing the three-screw technique (Figure 15.1), the most important screw is the posterior to anterior screw. The foot is maximally plantar flexed and a 3.2-mm double-ended guide (this may have to be pre-made) is placed through the distal tibial plafond and drilled retrograde so as to exit the posterior malleolus just proximal to the metaphyseal flare and lateral to the Achilles tendon. When the ankle is correctly positioned this pin should be situated so that when advanced it will eventually enter the center of the talar body and extend into the neck and head. Fluoroscopic control is very helpful when placing this guide pin. The guide pin is left flush with the tibial surface and is not advanced at this time.

Through a separate lateral stab incision a second 3.2-mm guide pin is placed just above the tibial metaphyseal flare anterior to the fibula (or through the fibula) and advanced to, but not across, the joint. In this manner, it can be visually confirmed that this second guide pin will exit the tibia in a position to enter the lateral talar body. A third 3.2-mm guide pin is placed through a medial stab incision in the same manner and its exit point from the plafond and its expected entrance point into the talus visually confirmed. By not advancing the pins, their positions can be verified to maximize later cannulated screw purchase.

Iliac crest bone graft is placed into the fusion site to improve contact between any areas of incongruity that remain after denuding and contouring the tibial and talar surfaces. The foot is now carefully returned to the original position selected for arthrodesis. This should be neutral plantar flexion and dorsiflexion with neutral to slight valgus angulation. The talus should be translated slightly posterior within the mortise. The guide pins are then advanced into the talus in the order in which they were initially placed to maintain the position for arthrodesis.

We prefer the use of stout (3.2-mm) guide pins that will hold the position of arthrodesis. Fluoroscopy is used to confirm arthrodesis position and guide pin locations. In the lateral view, the lateral guide pin should be anterior in the talus and the medial should be more posterior in its talar position. The guide pins are then measured with the direct reading depth gauge and the appropriate cannulated 6.5-mm self-tapping cancellous screws selected. The posteroanterior screw is placed first, followed by the lateral and

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FIGURE 15.4. Intraoperative fluoroscopy demonstrating final screw position prior to guide pin removal.

then medial screws. Additional bone graft is placed into a trough created in front of the ankle in a strain-relieving manner.[11] Final anteroposterior and lateral radiographs are obtained to ensure proper position and that the subtalar joint has not been penetrated (Figure 15.4).

The incisions are closed in layers over suction drainage. A well-padded posterior and U-shaped splint is applied. This is changed to a short leg cast at the time of suture removal. Partial weight bearing is allowed and progressed as radiographic evidence of union allows. Most patients are full weight bearing at 8 weeks and can be converted to a removable brace, which is worn only for weight bearing to a total of 12 to 16 weeks depending upon clinical evidence of fusion.

Uncomplicated situations with little or no malalignment may require only two 6.5-mm screws (medial-lateral) for satisfactory stabilization. When in doubt, the small additional time that it requires to place the anteroposterior screw is far less consequential than the risk of nonunion.

Lateral Approach

The lateral, or transfibular, approach is primarily used when anterior displacement of the talus in the ankle mortise exists, such as occurs following pilon fractures, and to remove previous internal fixation devices. This approach also can be utilized to expose the subtalar joint to perform pantalar arthrodeses. It may be coupled with a medial incision.

The distal fibula is exposed through a straight lateral incision. A 4- to 5-cm segment of fibula is removed exposing the ankle mortise. The talar and tibial surfaces of the ankle are denuded and any angulatory deformity corrected. Once the optimum position for fusion has been obtained the 3.2-mm guide pins are inserted. Under direct vision the same positioning of guide pins and self-tapping 6.5-mm cannulated screws, as was described for the anterior approach, is possible.

The removed section of distal fibula is then prepared for reinsertion. The lateral surfaces of the tibia and talus are denuded to bleeding bone, as is the opposing surface of the removed fibula. The distal fibular section is then secured to the tibia and talus with two additional lag screws placed through the fibula and into the corresponding tibia and talus.[11] This may be performed with 2.0-mm guide wires to give provisional fixation. The position is confirmed by fluoroscopy. The direct reading depth gauge is read and the 4.5-mm partially threaded self-tapping cancellous screws are passed over the

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guide wires. Bone graft is utilized as with the anterior approach. It is extremely important to restore the lateral integrity by replacing the fibula. We have recently treated three cases where the fibula was either not replaced or insecurely fixed that resulted in valgus malunions. The postoperative regimen is the same for both approaches.

Arthroscopic Approach

Our experience with arthroscopic-assisted ankle arthrodesis is still being assessed. Our general impression has been that while it is certainly viable, clear-cut advantages to open techniques remain to be seen. There is no question that the arthroscopic technique is best utilized in those patients whom have little or no deformity that requires correction.[13] Differences between open and arthroscopic methods in regard to postoperative pain, time to union, and nonunion rates still need to be assessed.

Our technique has utilized only two portals, anteromedial and anterolateral. A Zimmer ankle distractor is also used to improve visualization. A standard 4-mm, 30° arthroscope with a continuous pressure infusion irrigation setup is satisfactory in most cases. A 4.5-mm resector/shaver is used for the initial debridement, with more aggressive burs utilized as needed. It is important to debride all surfaces including the medial and lateral recesses. Ring curettes and pituitary rongeurs are very helpful in achieving complete debridement.

Once debridement is complete, the 3.2-mm guide pins are introduced percutaneously and their exits from the tibial plafond are visualized arthroscopically. Either two pins (medial and lateral) or three pins (posteroanterior, medial, and lateral) may be utilized. It is much more difficult to place the posteroanterior guide pin arthroscopically as it cannot be placed in an inside-out fashion as in the open technique. After placement of the guide pins, the foot is positioned and the guide pins advanced into the talus. Their positions and the position of the foot in relationship to the tibia is confirmed by fluoroscopy. The appropriate-length screws are determined with the direct reading depth gauge and then advanced over the guide pins and rechecked fluoroscopically. Routine closure and immobilization are utilized as in the open techniques.

Patient Review

In November 1993 we reported on our results in 42 patients (42 arthrodeses) utilizing the two- or three-screw internal compression technique and anterior approach. These were all performed for traumatic or inflammatory arthritis. Men outnumbered women 3 : 1. All patients went to successful union using the criterion of trabeculization across at least 50% of the joint on both the anteroposterior (AP) and lateral x-ray views and the patient could bear full weight on the ankle. The average time to union was 14 weeks.[12]

Difficult Ankle Arthrodeses

Several factors have been identified by multiple authors that may predispose patients to nonunion.[11,12,14] These include, but are not limited to, smoking, neurotrophic joints, talar osteonecrosis, pyarthroses, and extended hindfoot fusions. In our own series, utilizing the conventional compression screw arthrodesis technique, two of three patients with diabetic Charcot changes of the ankle went on to nonunion, and two of four patients treated for compensatory arthritis following previous subtalar arthrodesis developed nonunions. It is important to recognize that these conditions require additional considerations and methods of fixation.

Conclusion

While ankle arthrodesis remains the operation of choice for most patients with chronic painful conditions of the ankle, it is important to remember that it is a salvage operation. If reconstructive alternatives exist, they should at least be considered prior to fusion.[15] We feel that if arthrodesis is necessary, utilization of internal screw fixation for fusion is a reliable procedure. In most instances, it is well suited to

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the use of cannulated screws. No matter which surgical approach is utilized, the primary goal, in addition to union, is to obtain functional positioning of the foot. Patient satisfaction is highly dependent upon this. Unfortunately, no matter how good the union rates and initial patient satisfaction, gradual compensatory changes are inevitable in the subtalar and midfoot joints, and we should continue to search for a "better" procedure.

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