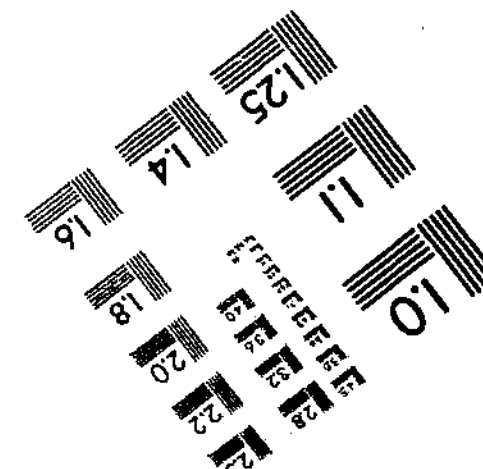
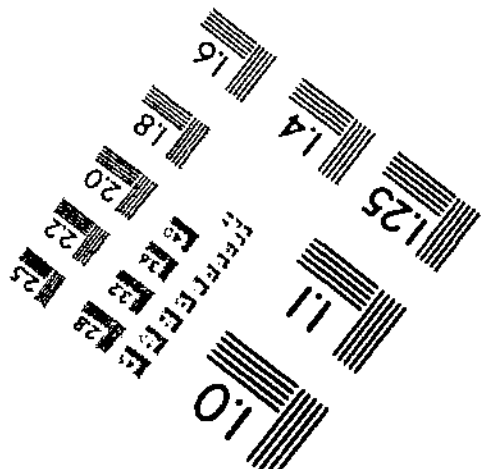
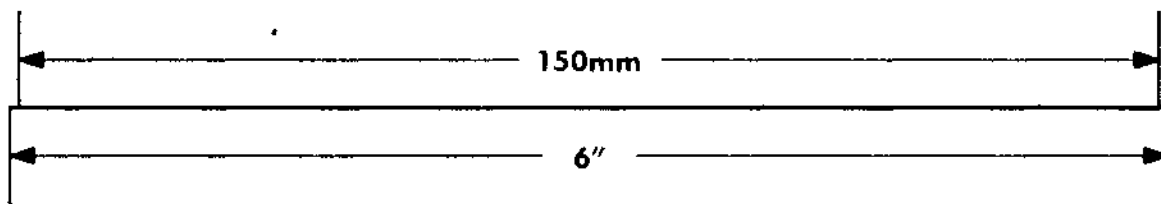
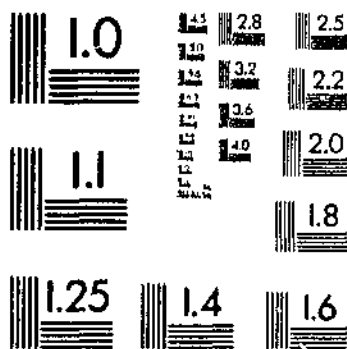
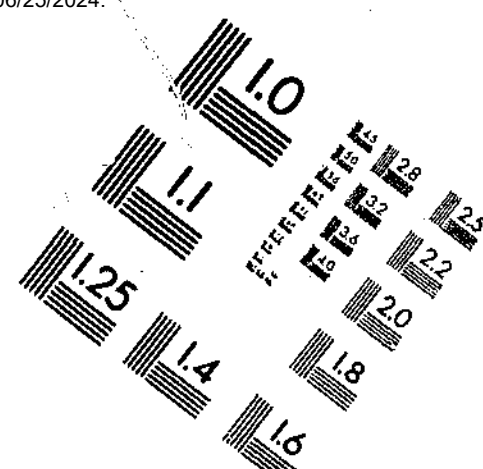
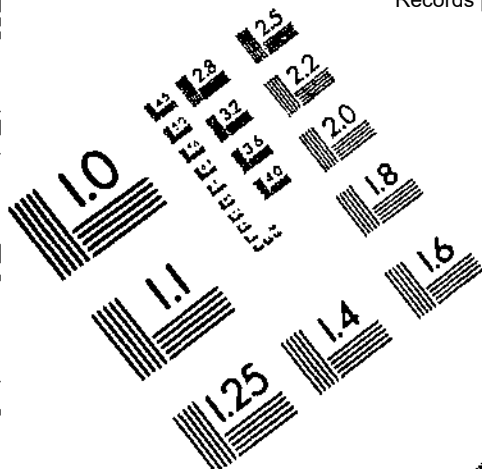


K 842493

87

IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION

770 BASKET ROAD
P.O. BOX 338

WEBSTER, NEW YORK 14580

Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FOI STATUS@fda.hhs.gov or 301.796.8118.

(716) 265-1600

K842493



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 13 1985 BEST AVAILABLE
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Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

John M. Agee, M.D.
The Hand Biomechanics Research Laboratory
77 Scripps Drive, Suite 101
Sacramento, California 95825

Re: K842493
Agee External Fixator

Dated: January 14, 1985
Received: January 22, 1985

Dear Dr. Agee:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HF2-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert G. Britain".

Robert G. Britain
Director
Office of Device Evaluation
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

From

Subject

To

REVIEWER(S) - NAME(S)

510(k) NOTIFICATION

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ☒ (A) Is substantially equivalent to marketed devices.
- ☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☐ (C) Requires more data.
- ☐ (D) Is an incomplete submission. (See Submission Sheet).

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COPY

Additional Comments:

S.E. to many external fixators or like
Richards, Acc, etc

The submitter requests:

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

Class Code w/Panel:

87 JEC
Component traction
INVASIVE

REVIEW:

(BRANCH CHIEF)

W. H. A.

2/8/85

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

Carl A. Larson

2/7/85

(DATE)

THE HAND BIOMECHANICS RESEARCH LABORATORY

JOHN M. AGEE, M.D.
DIRECTOR

77 SCRIPPS DRIVE - SUITE 101
SACRAMENTO, CALIFORNIA 95825
(916) 920-8054

January 14, 1985

BOB MANSELL
Center for Devices and
Radiological Health (HFZ-410)
FOOD AND DRUG ADMINISTRATION
8757 Georgia Avenue
Silver Springs, Maryland 20910

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RE: 510K Submission
Agee External Fixator
D.C. NO: K842493

Dear Mr. Mansell:

(b)(4); (b)(6)

510K SUBMISSION
Agee External Fixator
D.C. #K842493

January 14, 1985
Page 2

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(b)(4)

(b)(4)

If there is any additional information that you might need pursuant to our request for a 510K on this device, we would appreciate hearing from you.

Sincerely yours,

John Agee, M.D.

JOHN M. AGEE, M.D.

JMA:db
Enclosures

Page 08 of 36

Withheld pursuant to exemption

(b)(4) ; (b)(6)

of the Freedom of Information and Privacy Act

Page 09 of 36

Withheld pursuant to exemption

(b)(4) ; (b)(6)

of the Freedom of Information and Privacy Act

Page 10 of 36

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act

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Page 12 of 36

Withheld pursuant to exemption

(b)(4)

of the Freedom of Information and Privacy Act



Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

SEP 10 1984

The hand Biomechanics Research Laboratory
ATTN: John M. Agee, M.D.
77 Scripps Drive, Suite 101
Sacramento, CA 95825

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COPY

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

When your additional information is received by the ^{Office} of Device Evaluation the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and return it to you. Pursuant to 21 CFR 20.29, one copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or me at (301) 427-7230.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Memorandum

REVIEWER(S) - NAME(S)

Robert Mansell
K842493

510(k) NOTIFICATION

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ☐ (A) Is substantially equivalent to marketed devices.
- ☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☒ (C) Requires more data.
- ☐ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

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The submitter requests:

Class Code w/Panel:

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

REVIEW:

(BRANCH CHIEF)

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

(DATE)



JUN 27 1984

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

The Hand Biomechanics Research Laboratory
ATTN: John M. Agee, M.D.
77 Scripps Drive, Suite 101
Sacramento, CA 95825

D.C. Number : K842493
Received : 6-26-84
Product : Agee External Fixator

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

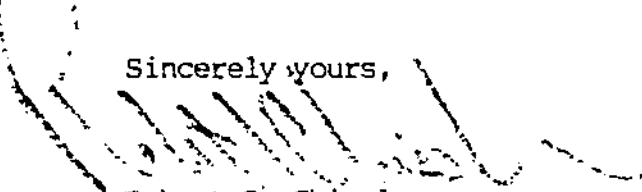
We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-7230.

Sincerely yours,


Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

K8412493

THE HAND BIOMECHANICS RESEARCH LABORATORY

77 SCRIPPS DRIVE - SUITE 101
SACRAMENTO, CALIFORNIA 95825
(916) 920-8054



W. M. AGEE, M.D.
DIRECTOR

FOOD AND DRUG ADMINISTRATION
Bureau of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Springs, Maryland 20910

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June 19, 1984

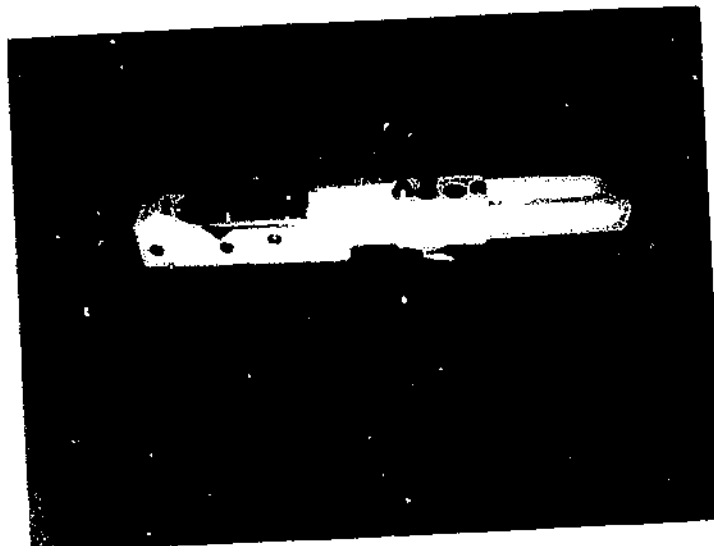
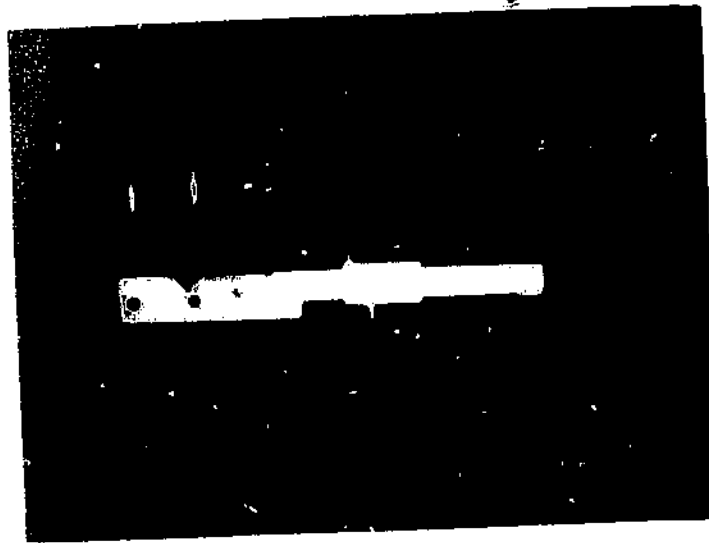
RE: 510K Submission
Agee External Fixator

Attention: Document Control Clerk

The Hand Biomechanics Research Laboratory is requesting marketing clearance for its Agee External Fixator to be distributed by Orthopaedic Moments. The pre-market notification information required by 21 CFR 807.87 is as follows:

RECEIVED
FDA/CDRH
JUN 26 AM 9:37
DOCUMENT CONTROL
CENTER

- a. Classification Name: Not listed.
Common/Usual Name: External skeletal fixator.
Proprietary Name: Agee External Fixator.
- b. Establishment Registration Number: 2919128.
- c. Classification: It is our opinion that this is a Class I device.
- d. Performance Standards: Not applicable.
- e. Label/Labeling/Advertisements: We are currently in the process of developing labeling, an application manual and promotional brochures (advertisements).
- f. Substantial Equivalence: This product is similar in design, composition and function to several external skeletal fixators including the Ace-Colles' Fixator and the Hoffmann External Fixation System. Copies of promotional literature for these two products are enclosed.
- g. Similarity to and Differences from Existing Devices on the Market: Please see attached document titled same.
- h. Device Materials: The load bearing portions of this device are manufactured from stainless steel and (b)(4) plastic. A set of internal brass gears are utilized to control and select displacement of the hand with respect to the forearm. One aluminum pivot plate is utilized together with the (b)(4) plastic to complete the assembly. The device is designed to be a one use disposable item. It will stabilize the patient's fracture by percutaneous pins manufactured by (b)(4) which is an established manufacturer of orthopaedic devices. Their "Certificate of Tests" and "Standard Specification for Fixation Pins and Wires" are enclosed. Enclosed also is a photograph of the device itself.



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COPY

510K Submission
Agee External Fixator
June 19, 1984
Page 2

The Hand Biomechanics Research Laboratory requests that the Food and Drug Administration hold as confidential information of our intent to market the Agee External Fixator.

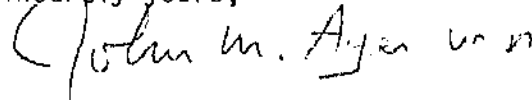
We consider our intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure. To the best of my knowledge, neither I nor anyone else has disclosed through advertising or any other manner our intent to market the device to scientists, market analysts, exporters, or other individuals except employees of, or consultants to our laboratory, or individuals in a marketing firm or law firm, pursuant to commercial arrangements with appropriate safeguards for secrecy.

We will immediately notify the Food and Drug Administration if we disclose the intent to market this device to individuals other than those directly associated with our institution, or its consultants and associates.

We understand that the submission of false information to the government is prohibited by 18 USC 1001 and 21 USC 331(q).

Please do not hesitate to contact me or Sue Agee at (916) 920-8051 if you have any questions regarding this submission.

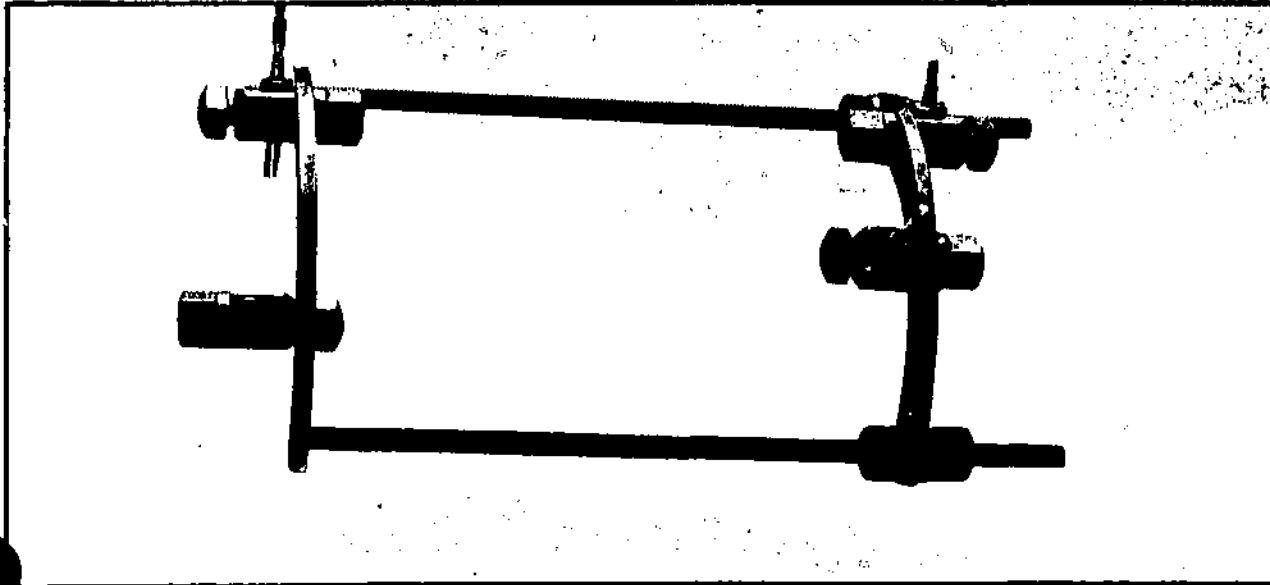
Sincerely yours,



JOHN M. AGEE, M.D.

JMA:db
Enclosures

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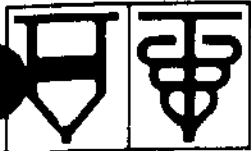


Patent Pending

ACE-COLLES' FIXATOR™

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ace ace orthopedic



YOUR TRAUMA COMPANY

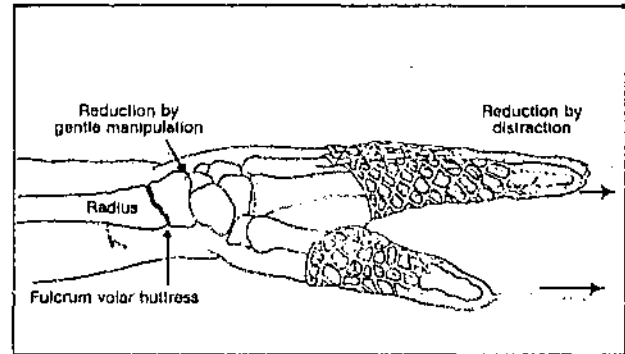
14105 South Avalon Blvd., Los Angeles, California 90061
Call 800-421-2871 (Outside California); or (213) 515-5443 (Inside California)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301.796.8118.

TECHNIQUE FOR

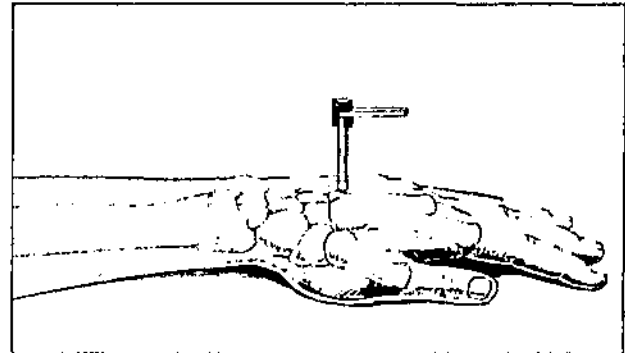
1

Brachial Block or Bier Block anesthesia is required. Finger trap suspension with 8-12 pounds of traction for 10 minutes is accompanied by a betadine prep and sterile drape. Closed reduction is obtained by gentle manipulation and direct manual compression. Hyperextension and flexion maneuvers are to be avoided.



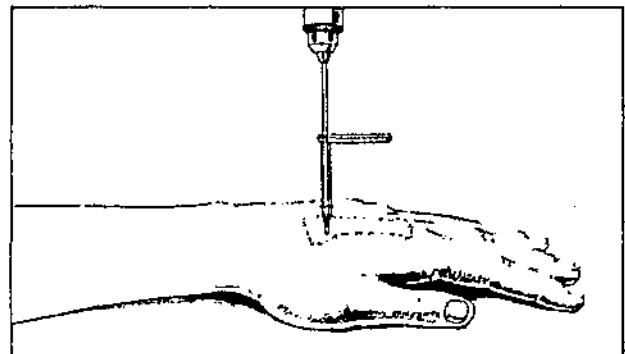
2

The proper placement of the first distal pin is into the base of the third metacarpal, avoiding the extensor tendons. A stab incision is made and the sheath and trochar are inserted to the bone.



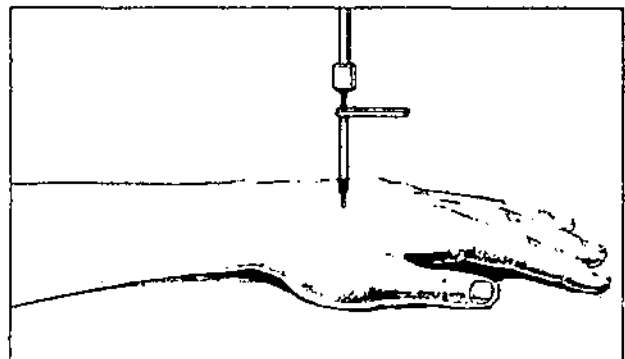
3

The trochar is then removed and the drill bit inserted and drilled through the bone. A low speed, high torque power drill is recommended.



4

Insert the pin through the sheath and into the bone using the pin inserter.



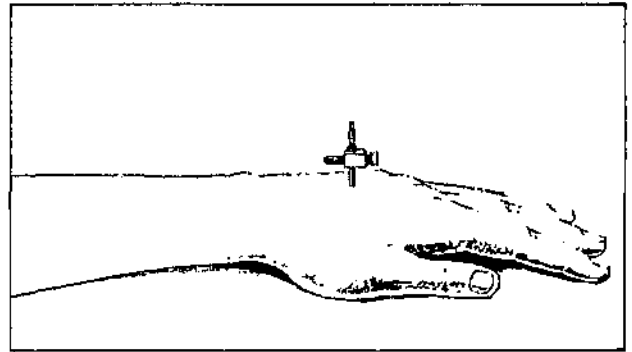
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APPLICATION

With instructions for
pin insertion
using the 3mm
Pre-drilled Pin System.

5

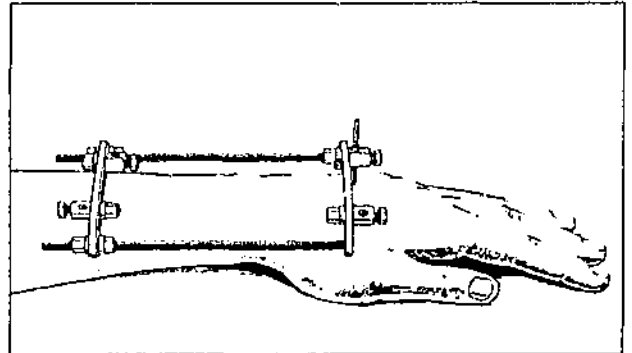
A one-pin holder with collet is placed over the pin. The bolt is tightened securing the pin holder to the pin.



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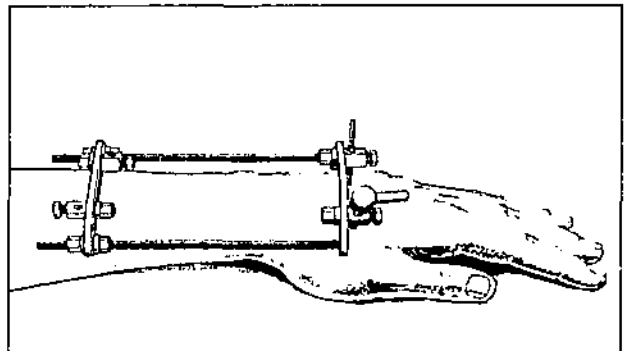
6

Attach the Colles' frame to the one-pin holder aligning it parallel to the radius. The frame then becomes the guide for placement of subsequent pins.



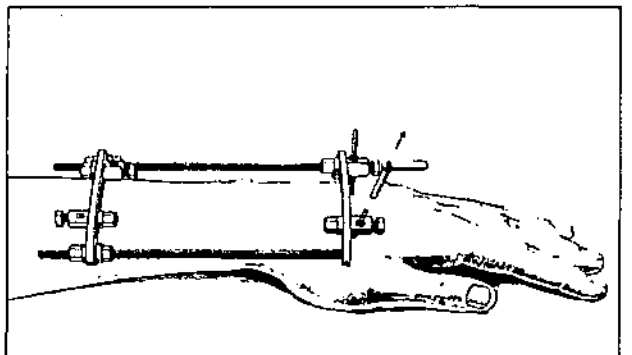
7

Using the second distal pin holder as a guide, the second distal pin is placed 60°-90° to the first pin into the second metacarpal base. Again, a stab incision is made. The collet is removed from the pin holder and the sheath and trochar inserted through the pin holder to the bone.



8

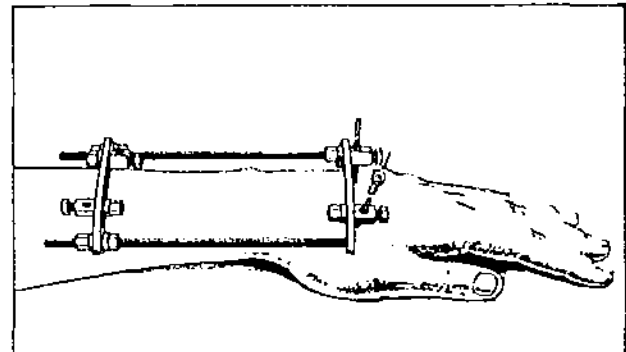
The previously described method for drilling and pin insertion applies. Following pin insertion, the sheath is removed.



9

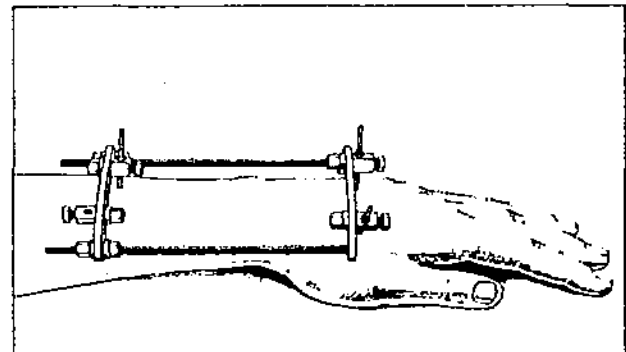
The collet is placed over the pin into the pin holder and the bolt tightened securing the pin holder to the pin. Distal pins should transfix both dorsal and volar cortices of each metacarpal.

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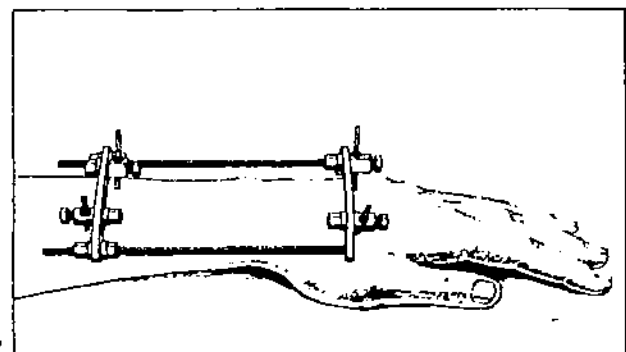
10

Two proximal pins are inserted 6-10cm proximal to the fracture site with the external fixator as the pin insertion guide. Following the steps for pre-drilled pin insertion, the pins are inserted directly down to the bone avoiding the extensor tendons and radial sensory nerve.



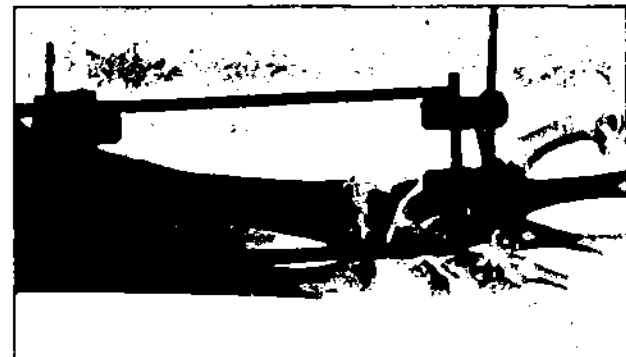
11

The external frame which was used as a pin insertion guide can now be appropriately tightened to secure the frame in place. Traction is maintained during pin insertion and pin guide tightening.



12

A-P and lateral roentgenograms confirm accurate reduction and pin placement. Full restoration of radial length, accurate volar cortical alignment and restoration of a volar neutral tilt to the distal radius should be present.



SUMMARY

Background of Distal Radius Fractures

Colles' fracture is probably the best known and most common fracture, recognized by both the medical profession and laity. It occurs at great regularity from falls on the outstretched hand and affects primarily women in the older age group. The incidence of fracture in this group is influenced by: a.) a decrease in bone strength associated with senile osteoporosis, b.) decreased neuromuscular coordination during ambulation, c.) external factors including inadequate traction surfaces (ice, snow, flooring), surface projections, and poorly designed foot gear. Though less common, it occurs in the younger age groups from severe trauma and results in distal forearm instability that requires vigorous treatment. A result less than near-normal will compromise occupational needs.



Problems in the Treatment of Colles' Fractures

There are a number of problems that arise with the treatment of Colles' fractures and may be for categorical purposes placed in a temporal sequence.

Acute

- Inadequate anesthesia (i.e. local hematoma infiltration).
- Difficult and unstable reduction maintained only by extreme positioning.
- Depressed major articular fracture components.
- Distal radio-ulnar joint injuries.
- Median nerve stretch, compression, contusion; occasional ulnar and radial nerve injuries.
- Post reduction swelling; constrictive dressing; Volkmann's contracture; early shoulder-hand dystrophy.
- Errors in external fixation.
- Tendon damage.

Subacute

- Loss of reduction and secondary deformity (radial shortening, dorsal angulation, dislocation distal ulna).
- Loss of fixation.
- Continued swelling—stiff hand.
- Shoulder-hand syndrome.
- Median nerve compression; radial cutaneous nerve compression.
- Intercarpal collapse deformity.

Late

- Loss of reduction and secondary deformity, the most common ones being:
 - a.) radial shortening.
 - b.) dorsal angulation.
 - c.) inadequate articular reduction.
 - d.) distal radio-ulnar dissociation and arthrosis.
- Extensor pollicis longus tendon rupture.
- Median nerve compression.
- Stiff hand; shoulder hand; post Colles' reflex dystrophy syndrome.
- Tenuous adhesions in the flexor compartment.
- Cosmetic dissatisfaction.
- Weakness associated with immobilization and shortening of skeletal segments, and changes in the force-moment arms particularly detrimental to efficient function of the wrist extensors.
- Radiocarpal arthrosis.
- Delayed union; nonunion.

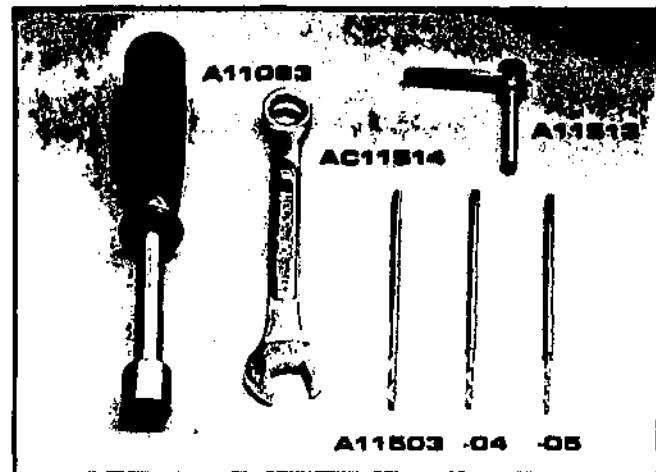
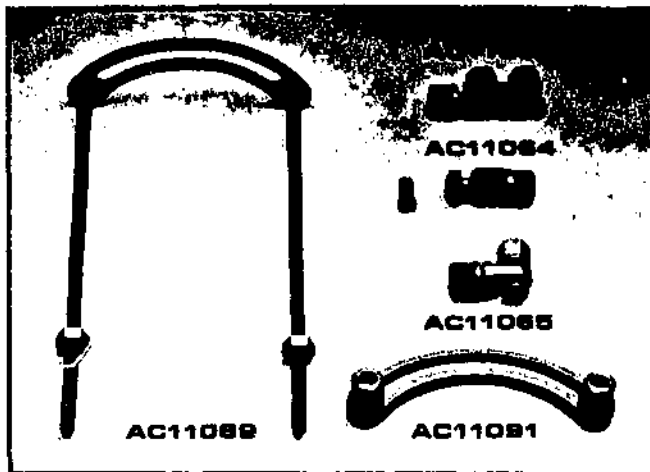
Indications for Treatment:

- Comminuted, intra-articular distal radius fractures. (Frykman—Classification III - VIII).
- Cotton-lander position necessary to obtain and maintain reduction ($>30^\circ$ flexion, 20° ulnar deviation).
- Failed closed reduction with casting.
- Bilateral Colles' fracture.

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PARTS



Parts List

Component Parts

- AC 11011-1** Complete 4" Colles' Frame (40°)
AC 11011-2 Complete 6" Colles' Frame (40°)
AC 11044-1 4" Ring Segment w/Rods (40°)
AC 11044-2 6" Ring Segment w/Rods (40°)
AC 11045-1 4" Colles' Frame w/o Pin Holders (40°)
AC 11045-2 6" Colles' Frame w/o Pin Holders (40°)
AC 11060 Ring Segment w/Nuts (40°)
AC 11064 Colles' Pre-drilled Pin Holder (w/Collet)
AC 11065 Pin Holder
AC 11072 Collet for AC 11064
AC 11078 Complete 6" Colles' Frame (84°)
AC 11084 2-Pin Holder
AC 11086-1 4" Colles' Frame (40°) w/AC 11064 Pre-drilled Pin Holder
AC 11086-2 6" Colles' Frame (40°) w/AC 11064 Pre-drilled Pin Holder
AC 11086-3 6" Colles' Frame (84°) w/AC 11064 Pre-drilled Pin Holder
AC 11088 6" Colles' Frame w/o Pin Holders (84°)
AC 11089 Ring Segment w/Rods (84°)
AC 11091 Ring Segment w/Nuts (84°)
AC 11019 Nut for AC11065
AC 11037 10mm. Jam Nut

Instrumentation

- AC11514** 10mm. Wrench
A11083 Dual Purpose Wrench/Insertion

Instrumentation

- A11503** 3mm. Drill Bit
A11504 2.5mm. Drill Bit
A11505 2mm. Drill Bit
A11513 Sheath & Trochar
A11515 Pin Insertion

Pre-Drilled Half Pins

- B3/75.15** 3mm. Half Pin (75mm. length, 15mm. thread)
B3/80.20 3mm. Half Pin (80mm. length, 20mm. thread)
B3/85.25 3mm. Half Pin (85mm. length, 25mm. thread)
B2.5/70.10 3mm. Half Pin (70mm. length, 10mm. thread)
B2.5/75.15 3mm. Half Pin (75mm. length, 15mm. thread)
B2.5/80.20 3mm. Half Pin (80mm. length, 20mm. thread)
B2/70.10 3mm. Half Pin (70mm. length, 10mm. thread)
B2/75.15 3mm. Half Pin (75mm. length, 15mm. thread)

Self-Drilling, Self-Tapping Half Pins

- BC 60.12** 3mm. Half Pin (60mm. length, 12mm. thread)
BC 80.16 3mm. Half Pin (80mm. length, 16mm. thread)
BCA110.21 3mm. Half Pin Interrupted Thread (110mm. length, 21mm. thread)
BCB110.21 3mm. Half Pin Continuous Thread (110mm. length, 21mm. thread)

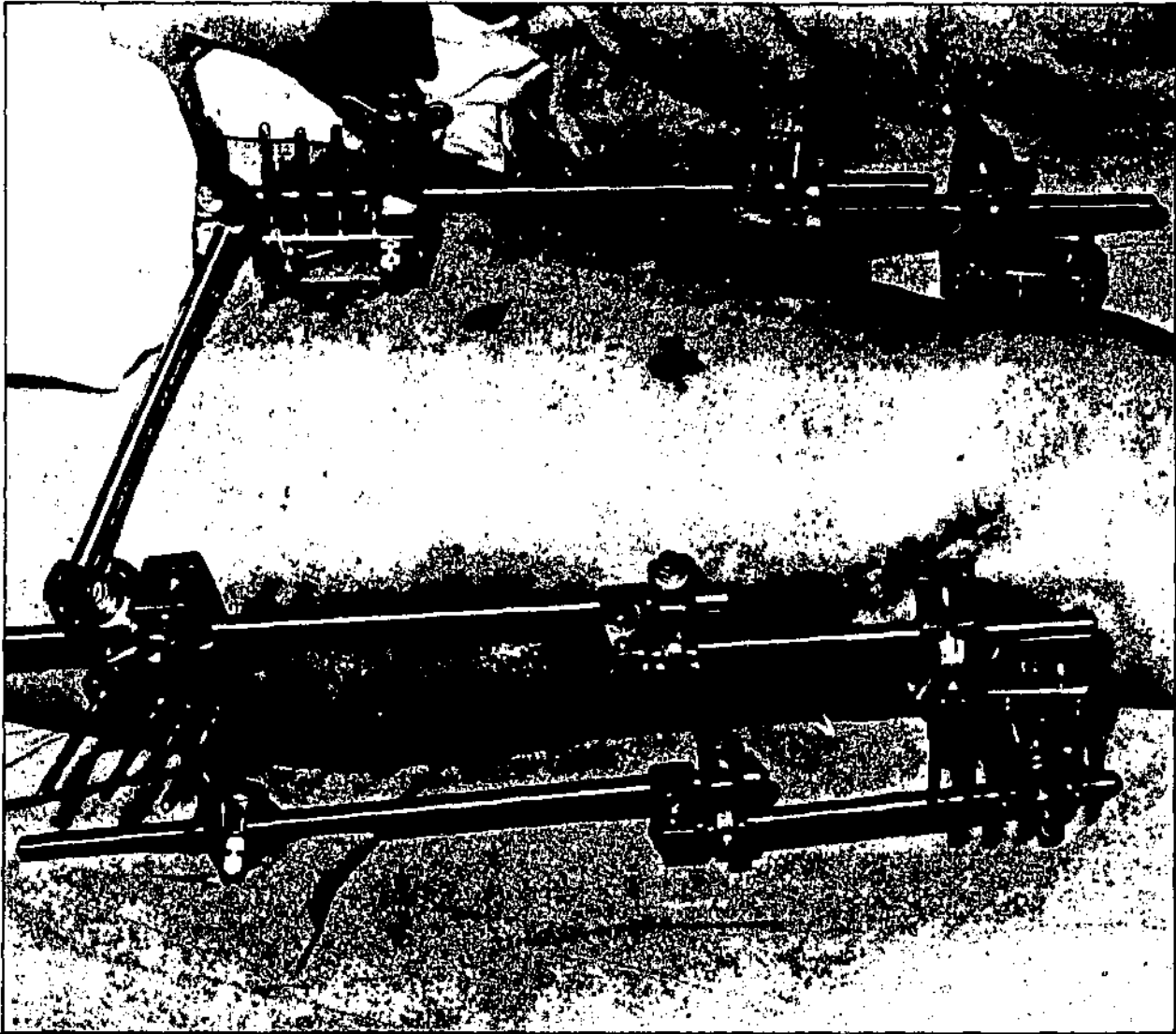
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Manufactured by:

ace orthopedic
 YOUR TRAUMA COMPANY
 14125 South Avon Blvd. Los Angeles, California 90061
 Call 800-421-2871 (Outside California) or (213) 515-5443 (Inside California)

Distributed by:

Howmedica's *Assurance of Quality...*

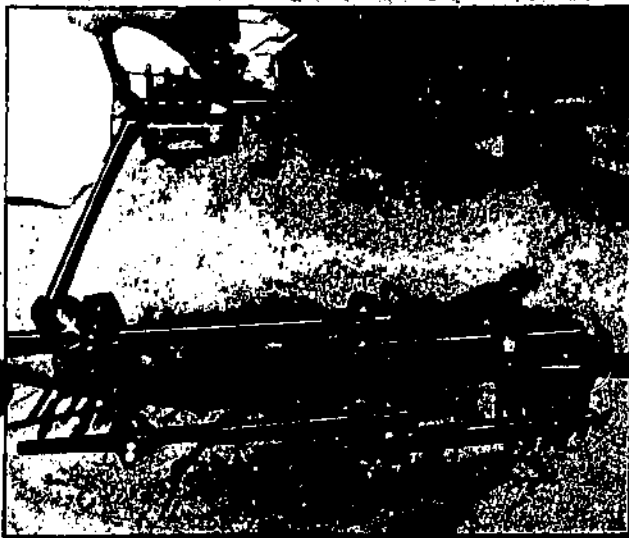


The Original **Hoffmann™** **External** **Fixation** **System***

BEST AVAILABLE
COPY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301.796.8118.

BEST AVAILABLE
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The Original Hoffmann™ External Fixation System*

INTRODUCTION

In 1938, Raoul Hoffmann, a Swiss Doctor of Medicine, designed an External Fixation System. The system was used with moderate success until 1968, when Professor Jaques Vidal, Chief Orthopaedic Surgeon of Montpellier Hospital in France, revised the original concept. The end result of Professor Vidal's work was the construction of a frame, which not only allowed for the reduction of the fracture after the frame assembly, but also provided the capability for rigidly stabilizing the most severe of long bone fractures.

Today, Howmedica is proud to be the exclusive distributor of the Original Hoffmann™ External Fixation Device.

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INDICATIONS

Primary:

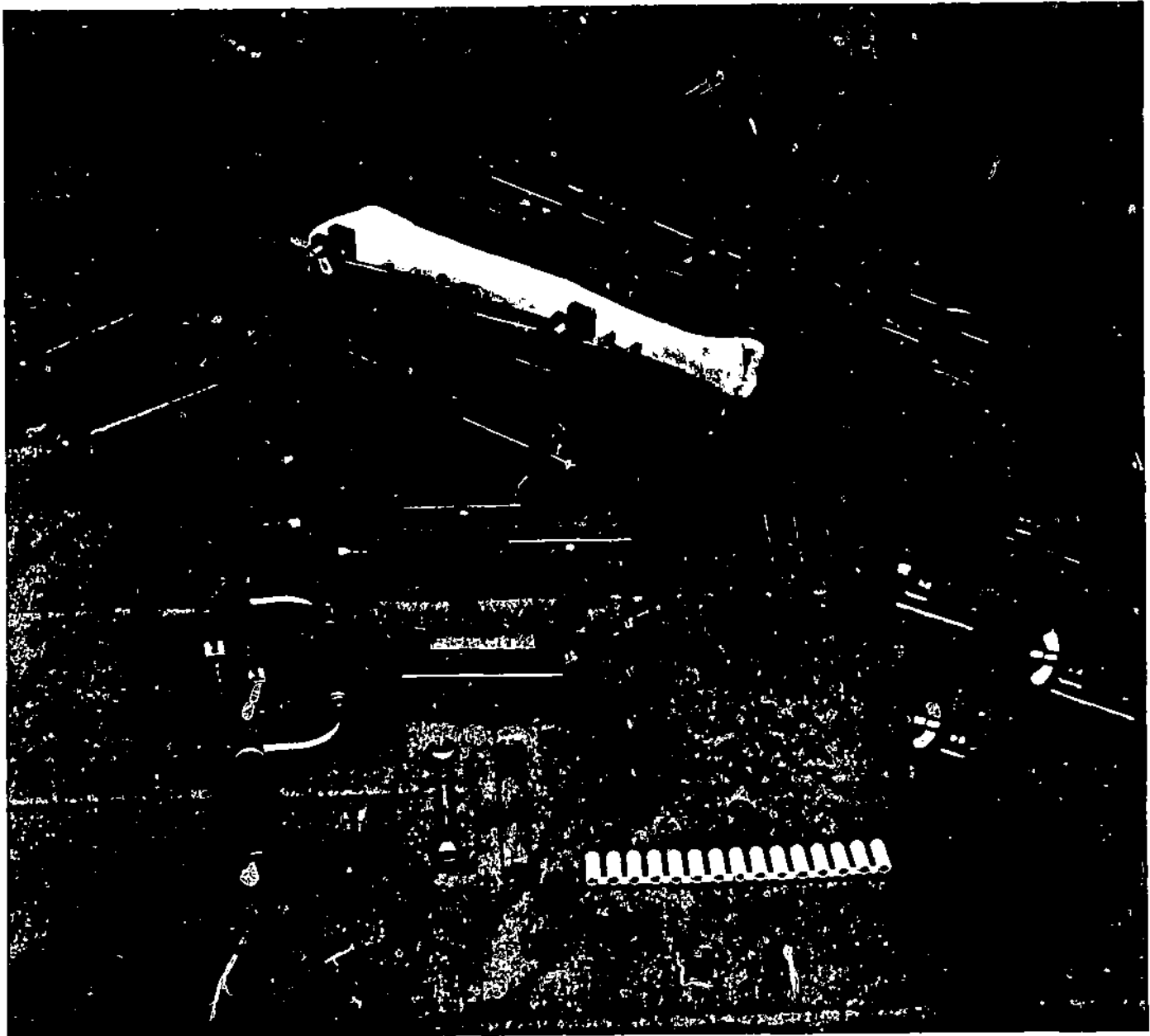
- Severe Open Fractures (grade 3)
- Highly Comminuted Closed Fractures
- Arthrodesis
- Infected Joints (arthrodesis & fractures)
- Infected Non-Unions

Secondary:

- Fracture Stabilization to Protect Arterial or Nerve Anastomosis
- Cross Leg Skin Grafts
- Three-Plane Corrections

The Original Hoffmann™ External Fixation System* is a proven method of fracture management that is extremely versatile in its usage. It employs percutaneous Half-Pins or Bonnel-Type Transfixing Pins which, when attached to a special external frame, form a rigid structure.





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The Original Hoffmann™ External Fixation System*

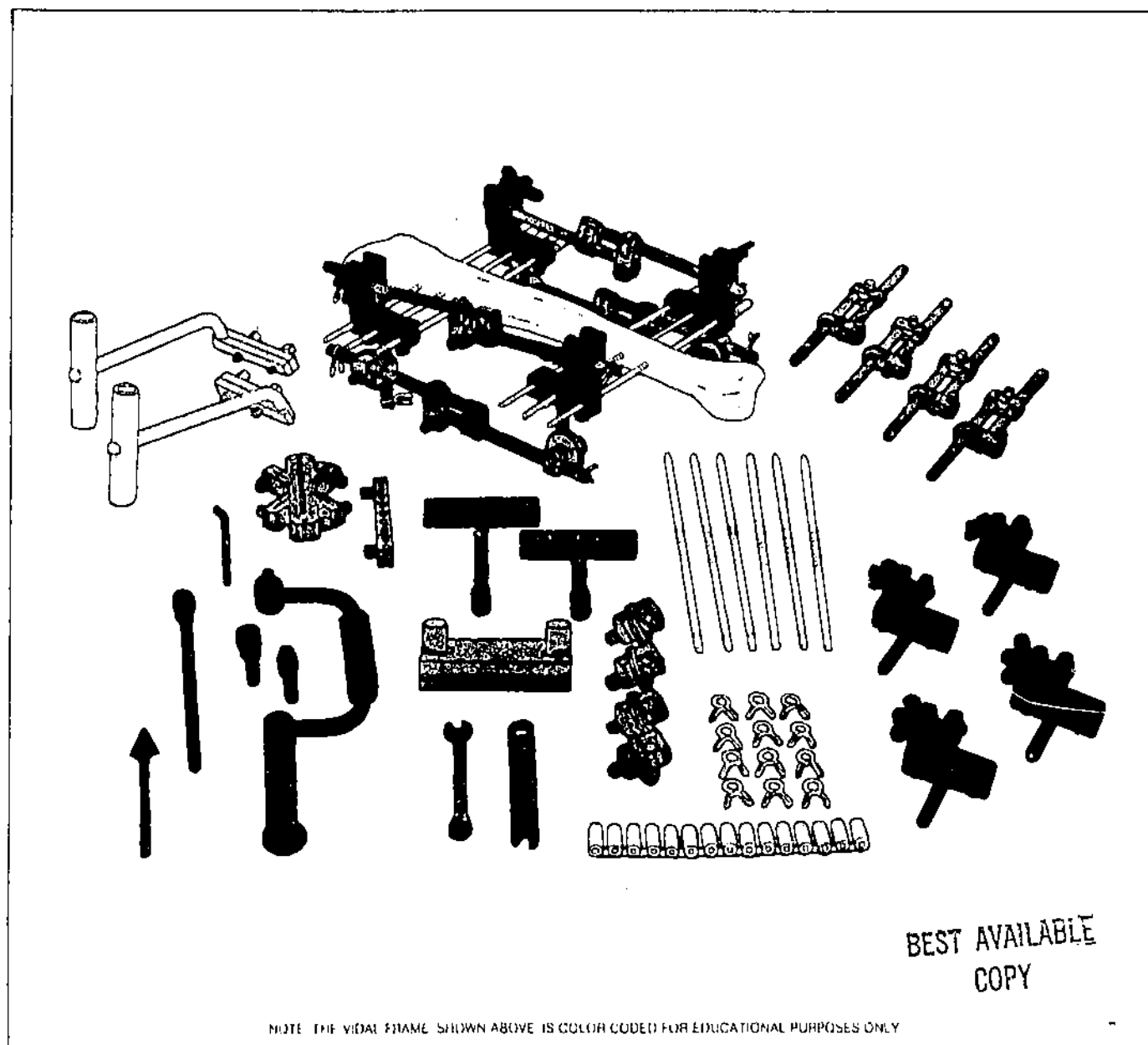
PROVEN APPLICATION TECHNIQUES FROM PRECISION DESIGN

All of the components of the System are made of stainless steel as shown in the above photograph. But, for educational purposes all of the components and instruments used in pin fixation and frame construction in this brochure will be color coded as shown on the opposite page.

INSTRUMENTATION

The Original Hoffmann™ System requires only a few multi-purpose instruments. These instruments allow the

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surgeon to locate the fracture fragments and place pins in parallel with accuracy, to reduce the fracture and to construct the frame.

Pins

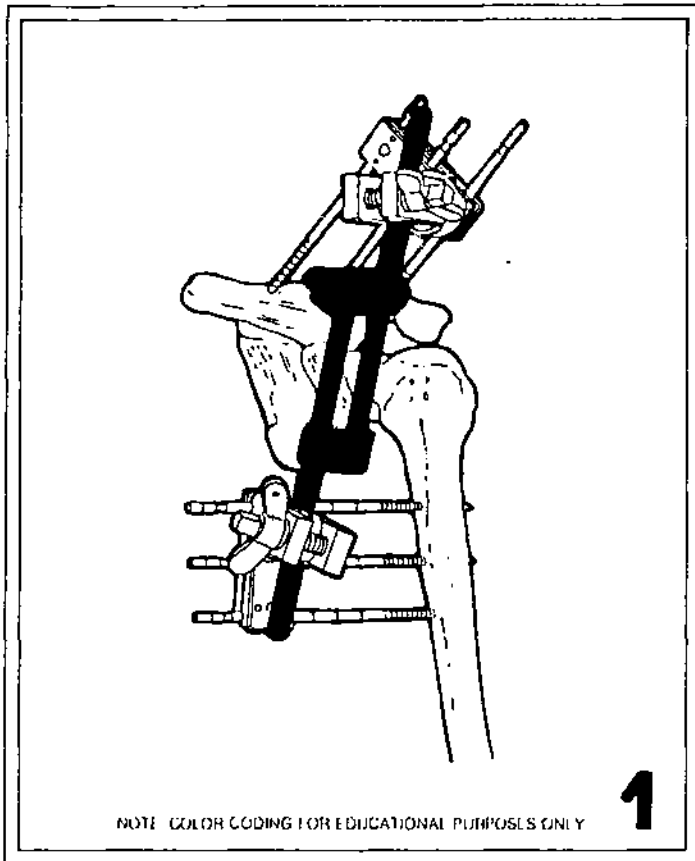
Two types of pins are used with the Original Hoffmann™ System: *Transfixing Pins* have a centrally located continuous thread, and are self-drilling and self-tapping. The *Half-Pins* have either continuous or interrupted thread for cancellous or cortical bone, and are also self-drilling and self-tapping.

Frame Components

Although there are a wide variety of frame components, only three are required for use in most ap-

plications. The other components are special purpose products for unusual situations and add to the overall versatility of the system.

**NOTE: COLOR CODING
FOR EDUCATIONAL
PURPOSES ONLY**

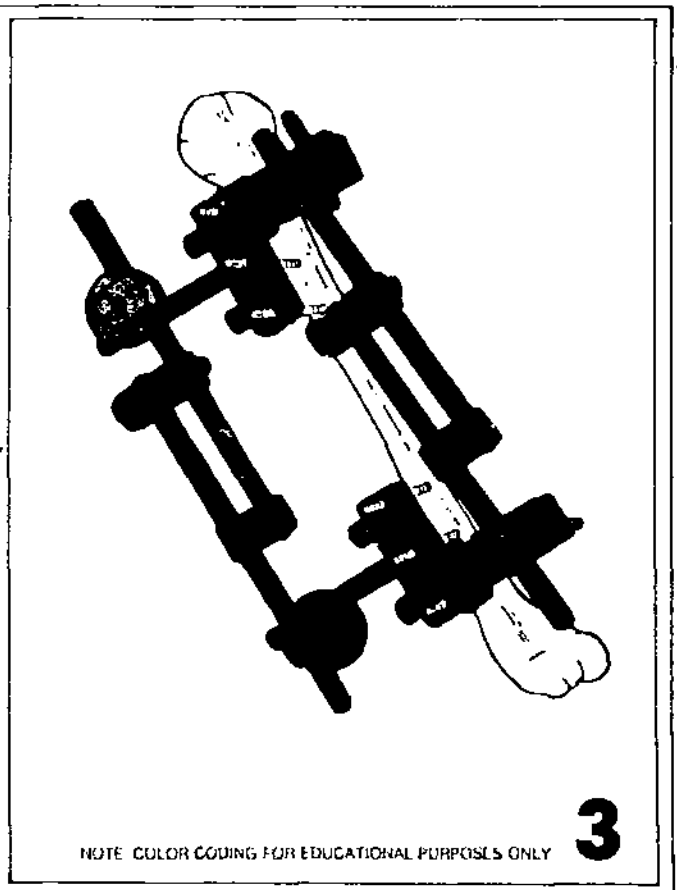
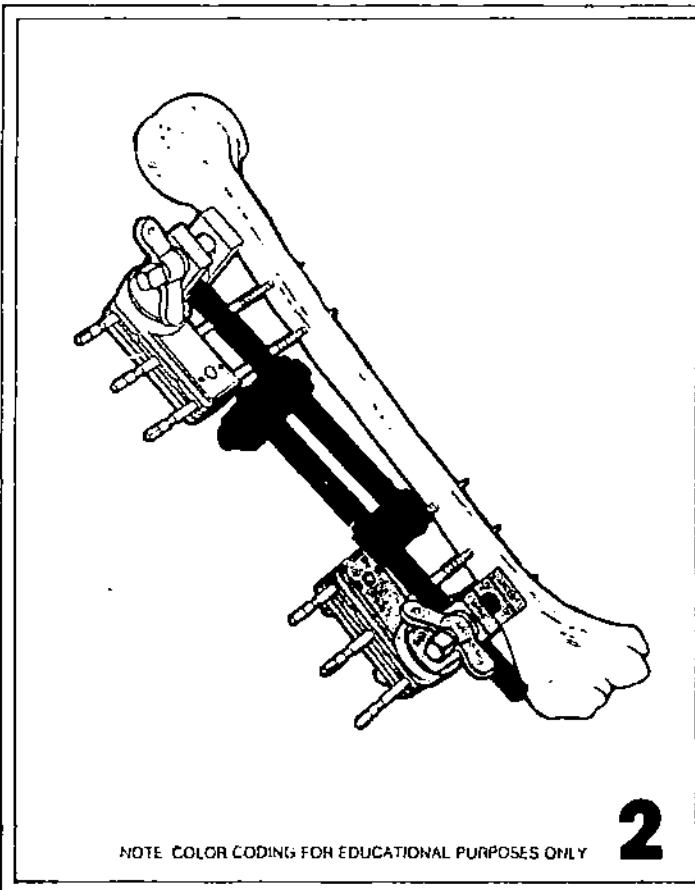


The Original HoffmannTM External Fixation System^{*}

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FRAME DESIGNS

The versatility of the Original HoffmannTM System is such that frame designs can be greatly modified to adapt to individual fracture situations. Various frame designs that have exhibited effective results are shown. Each of these frames can be revised to suit the surgeon's particular needs.



Shoulder Frame (Figure 1)

This frame is used primarily for shoulder arthrodeses, open highly comminuted fractures and infected non-unions.

Components Needed for this Mounting

- 6 Half-Pins
- 2 Universal Ball Joints
- 1 Adjustable Connecting Rod

Humeral Frames (Figures 2 & 3)

The Humeral Frame is primarily used for infected non-unions, severe open fractures and closed highly comminuted fractures. Single (Fig. 2) or double (Fig. 3) connecting rods can be used, depending upon the degree of stability required.

Components Needed for Single Mounting

- 6 Half-Pins
- 2 Universal Ball Joints
- 1 Adjustable Connecting Rod

Components Needed for Double Mounting

- 6 Half-Pins
- 2 Universal Ball Joint with Rods
- 2 Adjustable Connecting Rods
- 2 Articulation Couplings

Forearm Frame (Figure 4)

Forearm fractures of the severe open (grade III) type and infected non-unions are usually treated with 3mm pins and small size frame components.

Components Needed for this Mounting

- 6 Half-Pins
- 2 Universal Ball Joints
- 1 Adjustable Connecting Rod

Wrist Frame (Figure 5)

Fractures of the wrist can be treated by using the same frame design as that of the forearm, with half-pins being placed in the metacarpals.

Components Needed for this Mounting

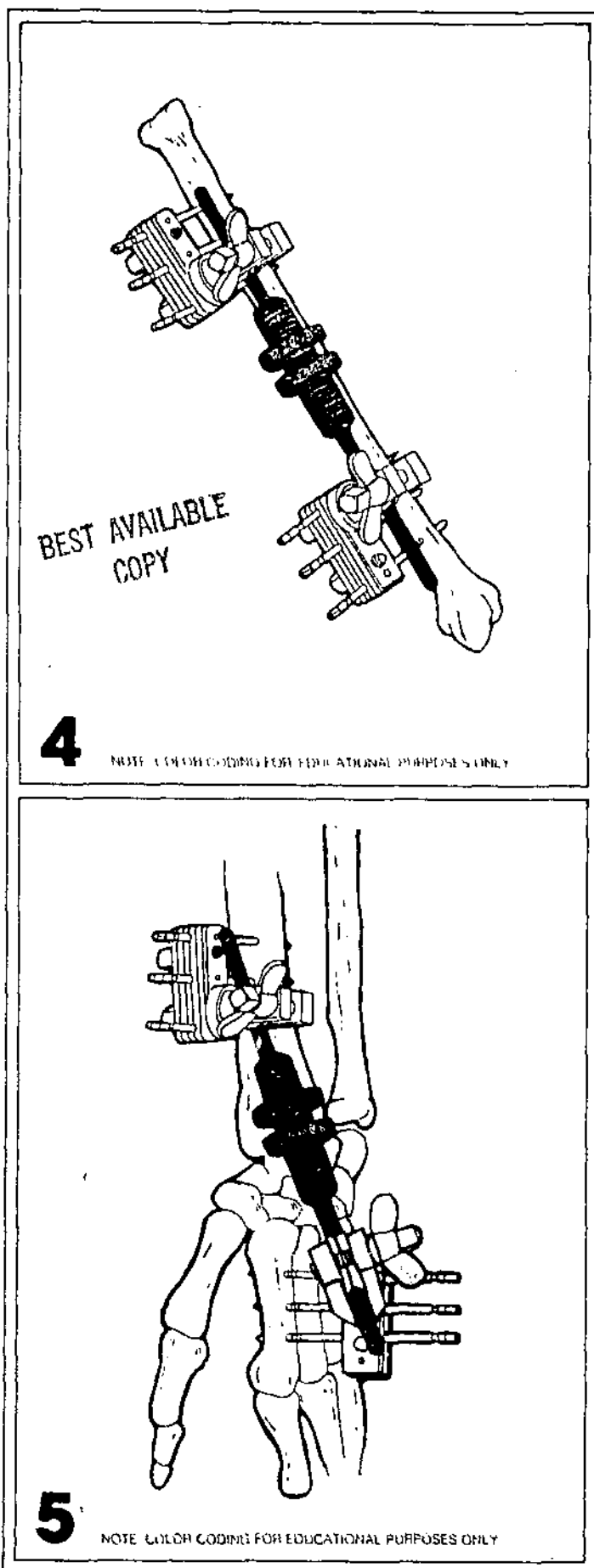
- 6 Half-Pins
- 2 Universal Ball Joints
- 1 Adjustable Connecting Rod

Elbow Frame (Figure 6) (see page 26)

The elbow frame is primarily used to obtain arthrodesis. The frame shown here is only one of the configurations that can be used, depending on the stability required, either a one-sided or double frame can be constructed.

Components Needed for this Mounting

- 6 Half-Pins
- 4 Universal Ball Joints
- 3 Adjustable Connecting Rods
- 3 Articulation Couplings
- 1 Connecting Rod (250mm or 300mm)



THE HAND BIOMECHANICS RESEARCH LABORATORY

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Similarity to and Differences from Existing Devices

The Agee External Fixator is substantially similar to other devices currently on the market in that it stabilizes an extremity fracture via percutaneous pins surgically implanted on either side of the fracture.

1. Intended Use: This device is intended to be used for unstable fractures of the distal radius and/or fracture dislocations of the carpus (wrist). In that regard, this device is similar to other external fixators currently on the market in terms of its potential efficacy in that a professional judgement is required by the treating physician with respect to the relative merit of this approach in each patient.
2. Operating Principles: This device is similar to current devices in that it is adjustable to allow for immobilization of the patient's fracture in the desired position. It is unlike other external fixators in that its design allows selective reduction of the fracture in three dimensions by movement of the hand (and therefore the wrist and distal fracture fragment) along and about three axes in space. The key difference is that each of the displacements along or about these axes occurs independently of the other two adjustments. The net benefit to the physician and his patient is that improvements in fracture reduction can be accomplished in one plane without compromising fracture reduction previously secured in a second or third plane.
3. Processing Procedures: As with other external fixators, this device is delivered to the physician or operating room nurses ready for sterilization by conventional steam autoclaving techniques. Although it is suitable for sterilization by gas (ethylene oxide) or ionizing radiation, in practice it will most often be "flash" autoclaved by steam.

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Page 33 of 36

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Standard Specification for FIXATION PINS AND WIRES¹

This Standard is issued under the fixed designation F 366; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval.

1. Scope

1.1 This specification covers acceptable dimensions and tolerances for pins and wires to be used by surgeons for fixation, traction, and other procedures in the treatment of a variety of patient problems and conditions.

1.2 In recognition of many broad and varied uses of such pins and wires many options are included. A variety, but not necessarily all, of the options are illustrated in Fig. 1.

NOTE—The values stated in U.S. customary units are to be regarded as the standard.

2. Applicable Documents

2.1 ASTM Standards:

- F 55 Specification for Stainless Steel Bars and Wire for Surgical Implants²
- F 56 Specification for Stainless Steel Sheet and Strip for Surgical Implants²
- F 67 Specification for Titanium for Surgical Implants²
- F 75 Specification for Cast Cobalt-Chromium Molybdenum Alloy for Surgical Implants²
- F 86 Recommended Practice for Surface Requirements of Metallic Surgical Implants²
- F 90 Specification for Wrought Cobalt-Chromium Alloy for Surgical Implants²

3. Material

3.1 Fixation pins and wires conforming to this specification shall be fabricated in accordance with one of the following ASTM specifications: F 55, F 56, F 67, F 75, or F 90.

4. Dimensions

4.1 Fixation pins and wires conforming to this specification shall be fabricated in accordance with the dimensions illustrated in Fig. 1.

5. Tolerances

5.1 Fixation pins and wires conforming to this specification shall be fabricated in accordance with the tolerances indicated for specific dimensions illustrated in Fig. 1. Where tolerances are not indicated for dimensions the following tolerances shall apply:

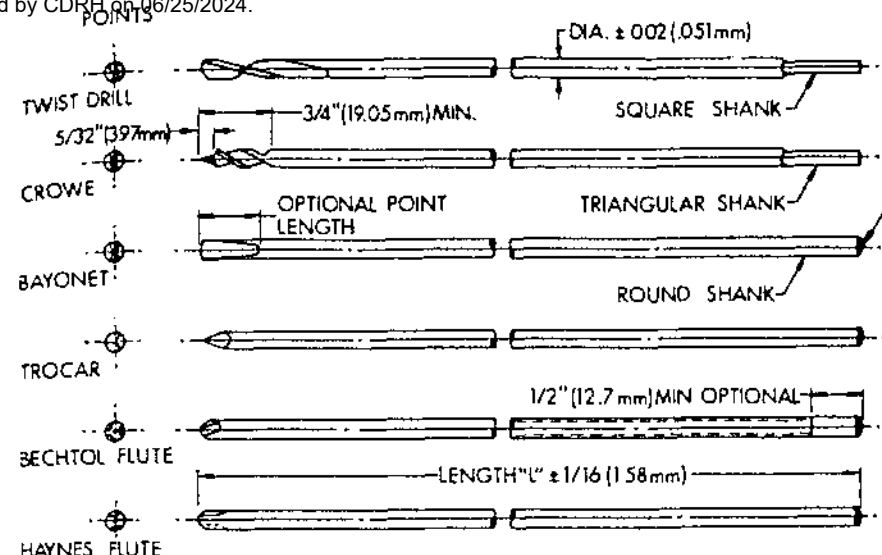
Fractional dimensions	$\pm \frac{1}{16}$ in. (0.40 mm)
Decimal dimensions	± 0.005 in. (0.13 mm)
Angles	± 2 deg
Metric dimensions	± 0.5 mm (0.019 in.)

6. Finish

6.1 Fixation pins and wires conforming to this specification shall be finished in accordance with Recommended Practice F 86.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Surgical Implants, and is the direct responsibility of Subcommittee F04.30 on Applications. Current edition approved March 29, 1973. Published June 1973.

² Annual Book of ASTM Standards, Part 7.



NOTE 1—Pins and wires may be smooth shank or threaded.
NOTE 2—Point angle and helix angle, where applicable, is as specified by manufacturer.
NOTE 3—On square or triangular shanks, flats are equal and corners are on the same circumference as the shank diameters larger than 1/4 in. (3.18 mm) may be reduced.
NOTE 4—Optional designs, both ends pointed or point with suture hole.

FIG. 1 Fixation Pins and Wires.

By publication of this standard no position is taken with respect to the validity of any patent rights in connection with the standard and the American Society for Testing and Materials does not undertake to insure anyone utilizing the standard against infringement of any Letters Patent nor assume any such liability.

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Page 36 of 36

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