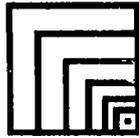


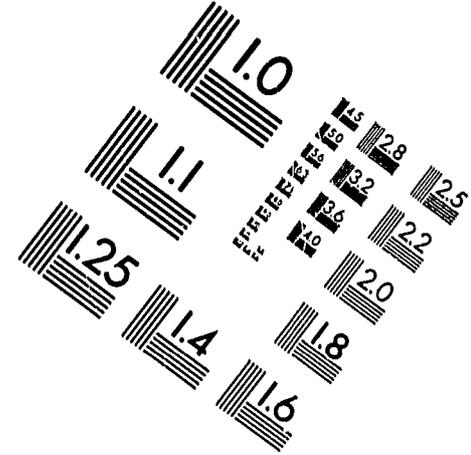
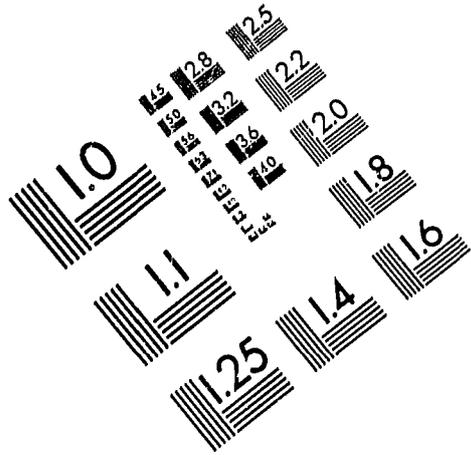
K 8 3 0 3 3 2

84

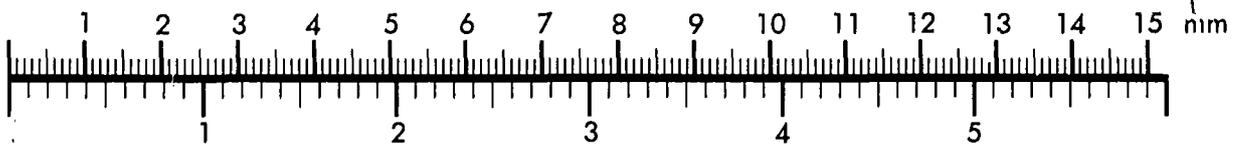


**NATIONAL
MICROGRAPHICS
ASSOCIATION**

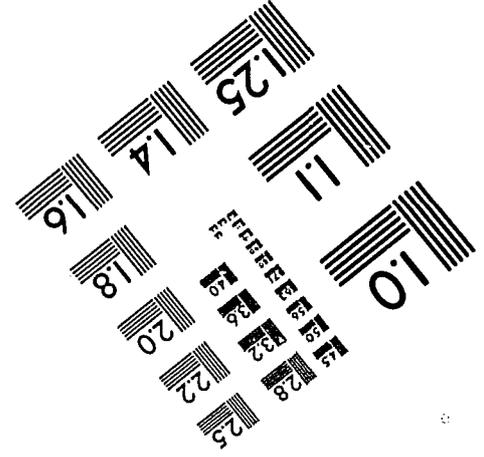
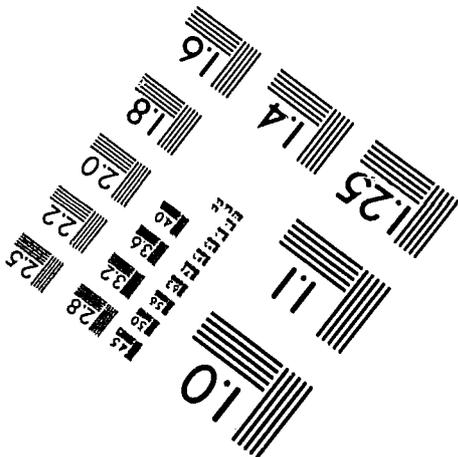
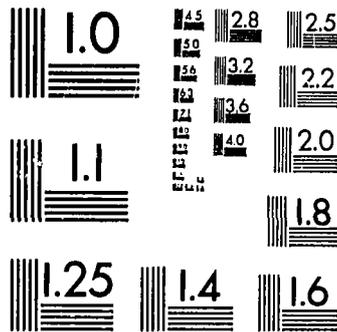
MS303-1980



Centimeter



Inches



K830332



MAR 2 1983

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Chris G. Klahm
Engineering Coordinator
for FDA Compliance
Ohio Medical Instrument Company, Inc.
315 West Liberty
Cincinnati, Ohio 45214

Ref: K830332 - Budde-Halo Retractor

Dated: January 24, 1983
Received: February 1, 1983
Regulatory class: II

Dear Mr. Klahm:

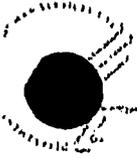
We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This product has been placed into the regulatory class shown above by a final regulation published in the Federal Register. Class I devices are regulated by the general control provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices are those for which future performance standards will be developed; class III devices are those which will be required to undergo premarket approval at some time in the future.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently 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. 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 need further assistance on the labeling for your device, please contact the Office of Medical Devices, Division of Compliance Operations (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date: 2/28/83
 From: Reviewer (s) - Name (s) A Doyle Gantt
 Subject: 510(K) Notification K830332
 To: 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:

Class Code w/ Panel:

classification based on
882.4800
Self-Retaining Retractors for Neurosurgery

84GET

REVIEW: [Signature] 2/28/83
 BRANCH CHIEF DATE

FINAL REVIEW: [Signature] 2/28/83
 DIVISION DIRECTOR DATE

OPTIONAL REVIEW: _____
 ASSOC. DIRECTOR FOR DEVICE EVAL. DATE

BEST AVAILABLE COPY

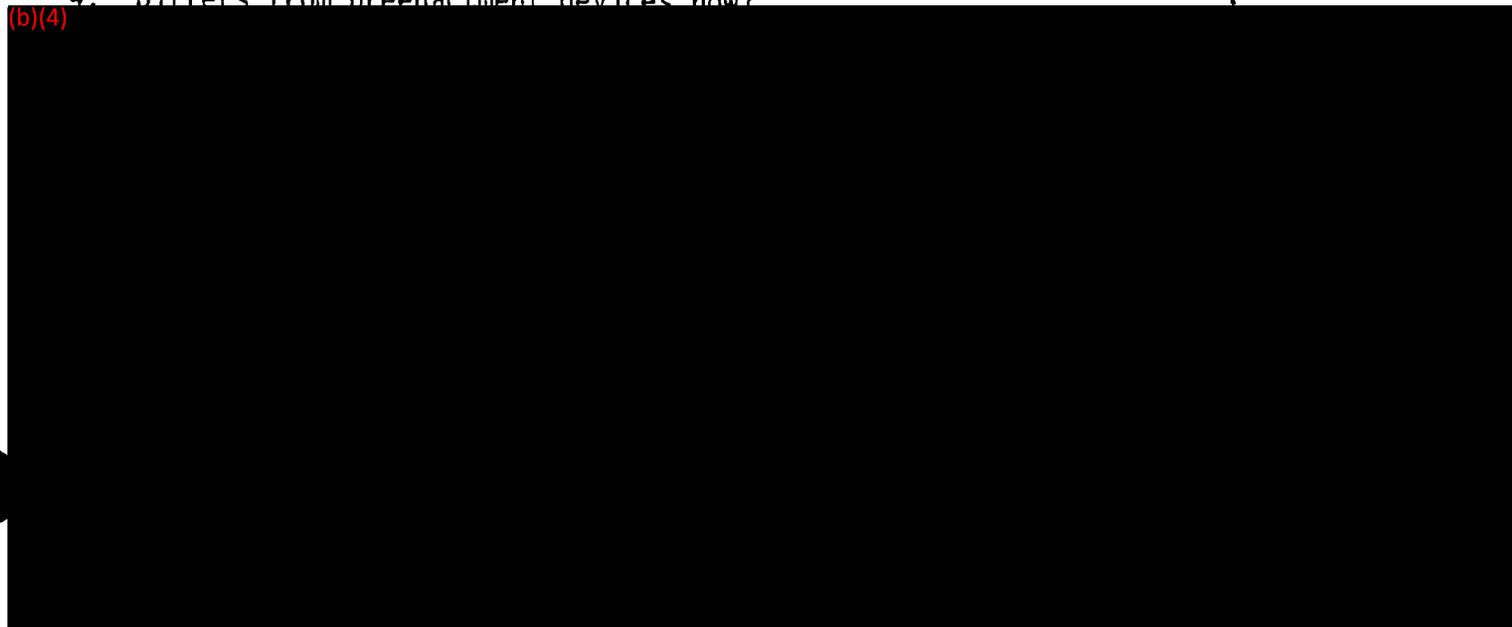
Company Name Ohio Medical Instrument Co, Inc. K830332

Device Name Budd - Halo Retractor

	YES	NO
1. Life-supporting or life-sustaining?	<u> </u>	<u> </u>
2. Implant (short-term or long-term)?	<u> </u>	<u> ✓ </u>

3. Similar preenactment device(s): Greenberg Retractor + Handrest
(device name, manufacturer)
Codman + Shurtliff

4. Differs from preenactment devices how?



5. If appropriate: provides comparative in vitro data: No
 provides a summary of animal testing? No
 provides a summary of clinical testing? No

6. I believe this is equivalent to device(s): # 84G2T
Classification should be based on:

Subsection Self-retaining Retractors for Neurosurgery (presently Class II).
682.4800 (name)

AD Grant 2/28/83
(sign & date)

I believe this is not equivalent to any preenactment device.

I believe clinical testing is required before a determination can be made.

BEST AVAILABLE COPY

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 2/23/83
FROM: Biomedical Engineer #FK430	OFFICE AODE	
TO: K830332	DIVISION DAND	

SUBJECT: Memorandum of a Telephone Conversation

SUMMARY
I talked with Mr. Klahm today and discussed the following concerning his 510(k) for the Budd-Halo Retractor:



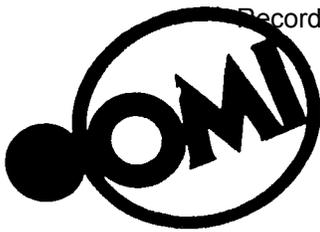
(b)(4)

cc: Grant / Carson

A. Doye [Signature]

BEST AVAILABLE COPY

SIGNATURE	DOCUMENT NO.
-----------	--------------



OHIO
MEDICAL
INSTRUMENT
COMPANY, INC. 315 WEST LIBERTY, CINCINNATI, OHIO 45214 513/579-1661

January 24, 1983

K830332

RECEIVED
FEB - 1 1983
FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE

Document Control Center
Bureau of Medical Devices (HFK-20)
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

Ref: 510K Submission
BUDE-HALO RETRACTOR

Attention: Document Control Clerk

Gentlemen:

OHIO MEDICAL INSTRUMENT COMPANY, INC. is requesting marketing clearance for its Halo Retractor. The Premarket Notification information requested by 21CFR 807.87 is as follows:

- a) Classification Name: Self Retaining Retractor
for Neurosurgery
Common/Usual Name: Halo Retractor
Proprietary Name: Budde-Halo Retractor
- b) Establishment Registration No: 1525725
- c) Classification: 21 CFR 882.4800 (April 1, 1982)
states that Self-Retaining Retractors
for Neurosurgery are classified as a
Class II Device.
- d) Performance Standards: At this time, there are no applicable performance standards for this device (according to Section 514;1976 Medical Device Amendments). Of course, OMI, Inc. does adhere to the GENERAL CONTROLS sections of the Medical Device Amendments, particularly the GMP clause (Section 520(F)).

BEST AVAILABLE COPY

January 24, 1983

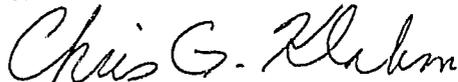
e) Label/Labeling/Advertisements: The enclosed Product Instruction Manual (See Exhibit I) will illustrate and describe the function of this product. The only other labeling utilized with the Halo Retractor is represented by the enclosed label facsimile (See Exhibit II). The words 'BUDE-HALO RETRACTOR' are etched by electrolysis on the carrying (sterilizing) case. The OMI sticker is attached just beneath the etching.

f) Substantial Equivalence: The Budde-Halo Retractor is similar in design, composition, and function to the GREENBURG RETRACTOR AND HAND-REST, marketed by CODMAN & SHURTLEFF, INC. (Randolph, Massachusetts). (See Exhibit III)

We would appreciate your earliest attention to this 510K submission, in order that we can obtain FDA compliance and offer this device for sale. If you need further information, please contact me at (513) 579-1661.

Cordially,

OHIO MEDICAL INSTRUMENT COMPANY, INC.

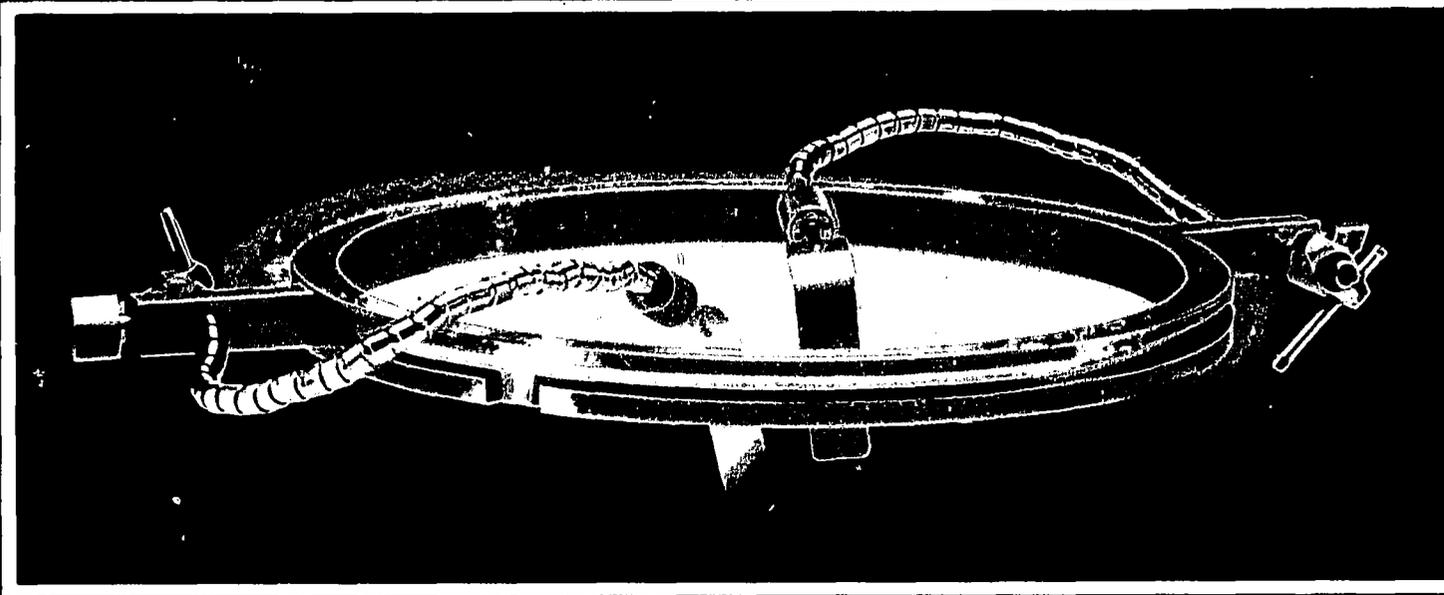


Chris G. Klahm
Engineering Coordinator for FDA Compliance

CGK/da

BEST AVAILABLE COPY

BLANK PAGE

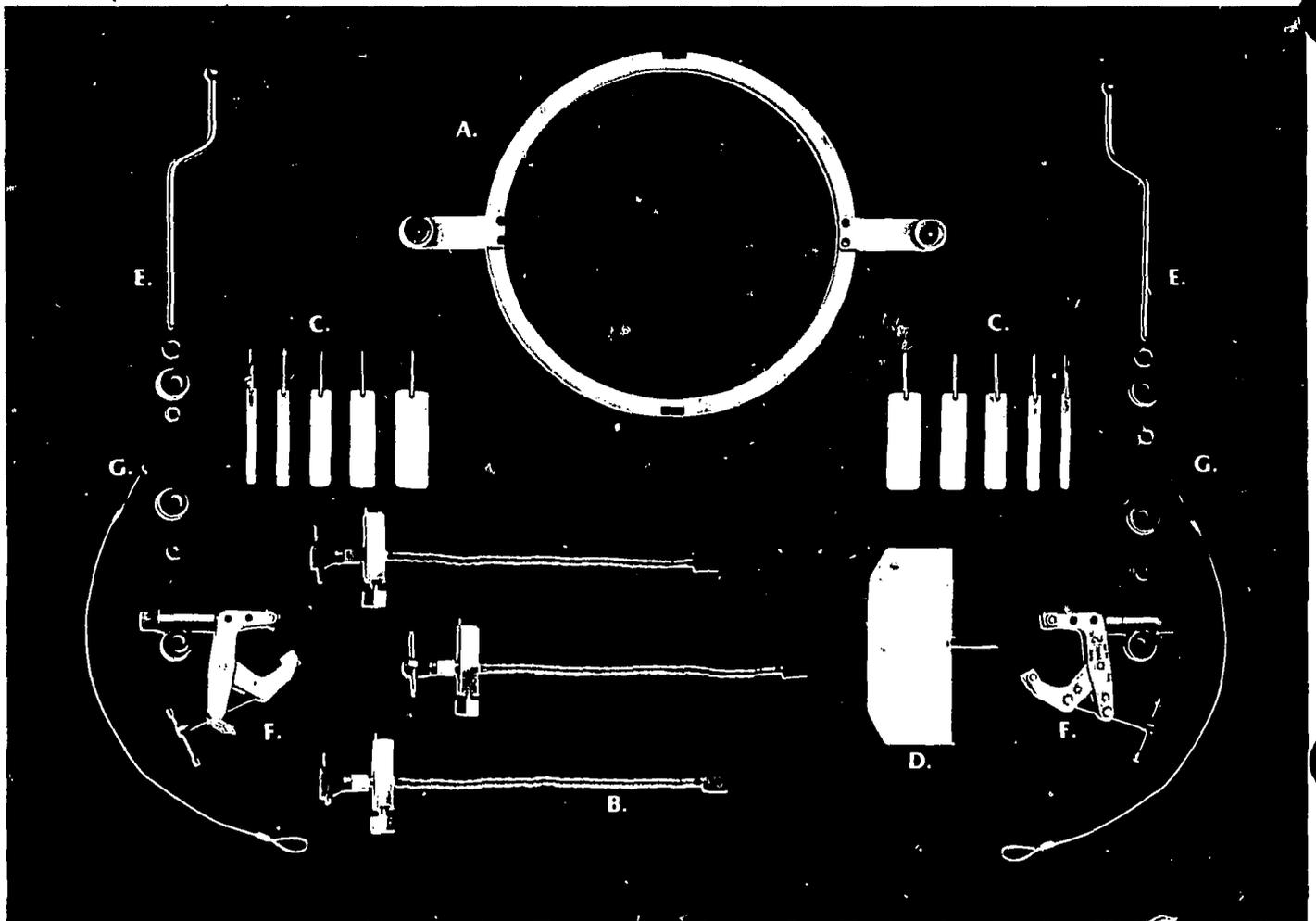


Budde-Halo Retractor

Designed By Richard B. Budde, M.D.
In conjunction with the Mayfield
Neurological Institute and Ohio Medical
Instrument Company Inc.

The Budde-Halo Retractor was designed for use in all craniotomies where tissue retraction is required. Attachment to the Skull Clamp is made after draping is completed, thus allowing the surgeon to bring the unit into the operating field at any stage of the procedure. With the low profile circular structure balljoint fixation, positioning of the retractors is unlimited. Along with a built in hand rest, this design permits the surgeon to work in an area where unrestricted hand movement is possible. Working with the Retractor Arms over or under the Halo Ring depends upon the procedure being performed and the surgeon's preference after familiarization with the equipment. Either method will give a secure low profile Retractor System. The system comes complete in a kit form with a case for ease of storing and sterilization.

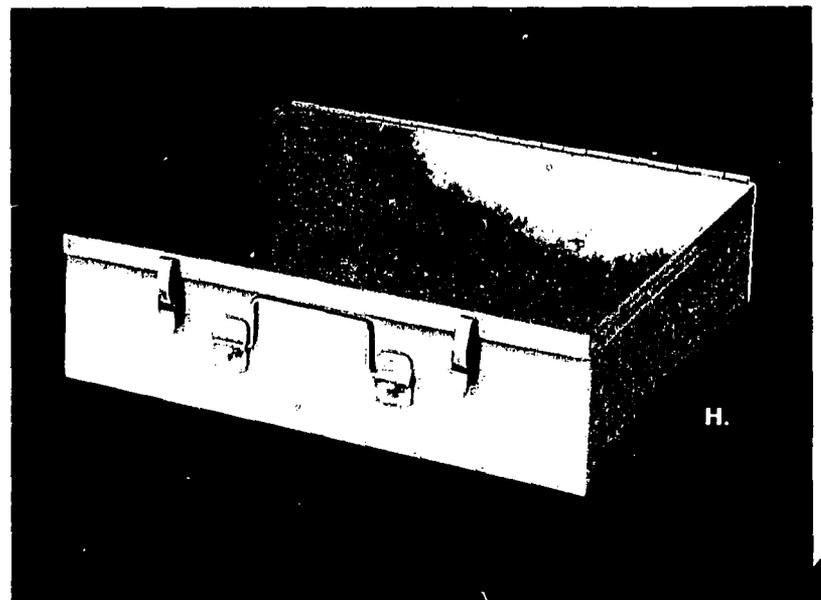
RETRACTOR KIT A-1040



Retractor Kit A-1040 Includes

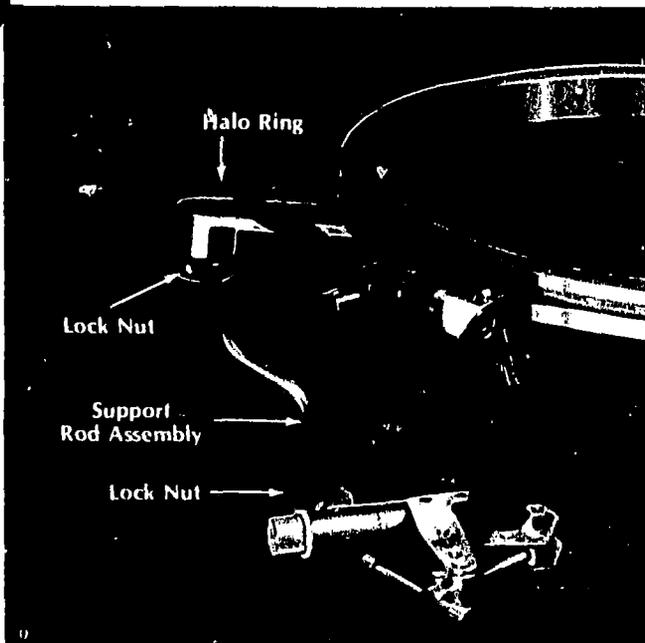
- A. (1) Halo Ring
- B. (3) 9" Retractor Arm
- C. (1) 4" Retractor Blade Kit*
- D. (1) Patty Tray
- E. (2) Support Rod Assembly
- F. (2) Support Bracket Assembly
- G. (2) Adjustment Wrench
- H. (1) Sterilizing Case

* Retractor Blade Kit consists of two each 1/4, 3/8, 5/8, 3/4, & 1"

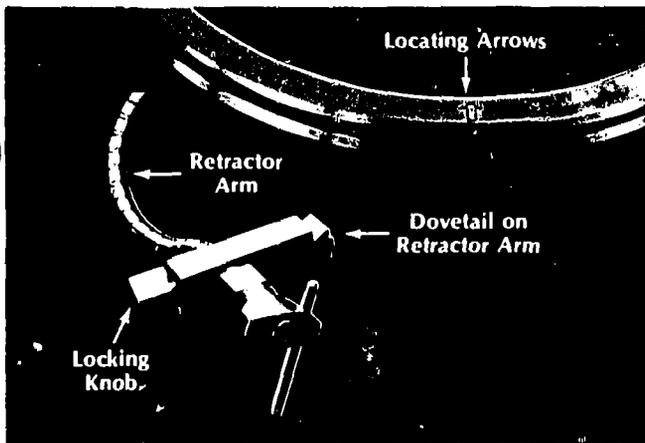


BEST AVAILABLE COPY

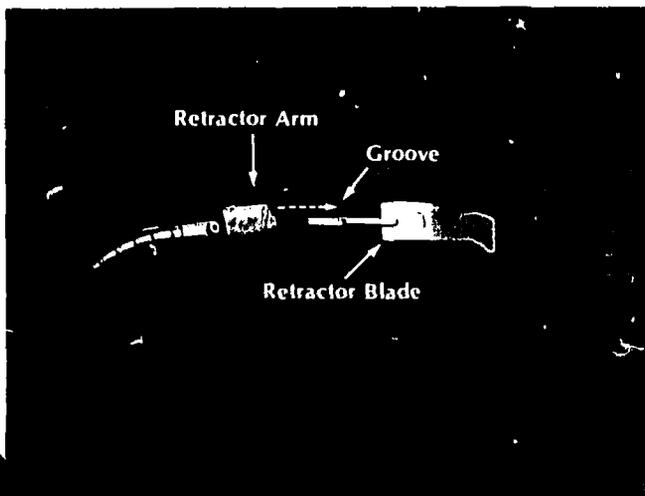
General Set Up Procedures



A. Attachment of the support rod assembly to the Halo Ring should be made with a hand tight fastening of the lock nuts. This will allow for movement of the balljoint when positioning the ring over the operating field. Loosen the locking nuts on the support brackets to allow the support rods to slide thru. Again hand tightening the locking nuts will allow for movement while still holding the Halo Ring in position. Adjust the ring to the desired location and secure all four lock nuts using the Lock Wrench.



B. Attachment of the Retractor Arms is accomplished by locating the openings directly under the arrows on either side of the ring and sliding the dovetail section of the Retractor Arm Bracket into the groove. After locating the desired number of arms in the position you wish, make sure each is securely locked using the knob on the end of the Retractor Arm Bracket.



C. The Retractor Blade Stems have a groove on one side which must line up with a centering dot that appears on the chuck of the Retractor Arm Assembly. By holding the Retractor Arm in your hand so as to be able to grasp the chuck with your thumb and forefinger, you will be able to push the chuck forward thus allowing the Retractor to be inserted. Removal of the Retractor requires the same technique.

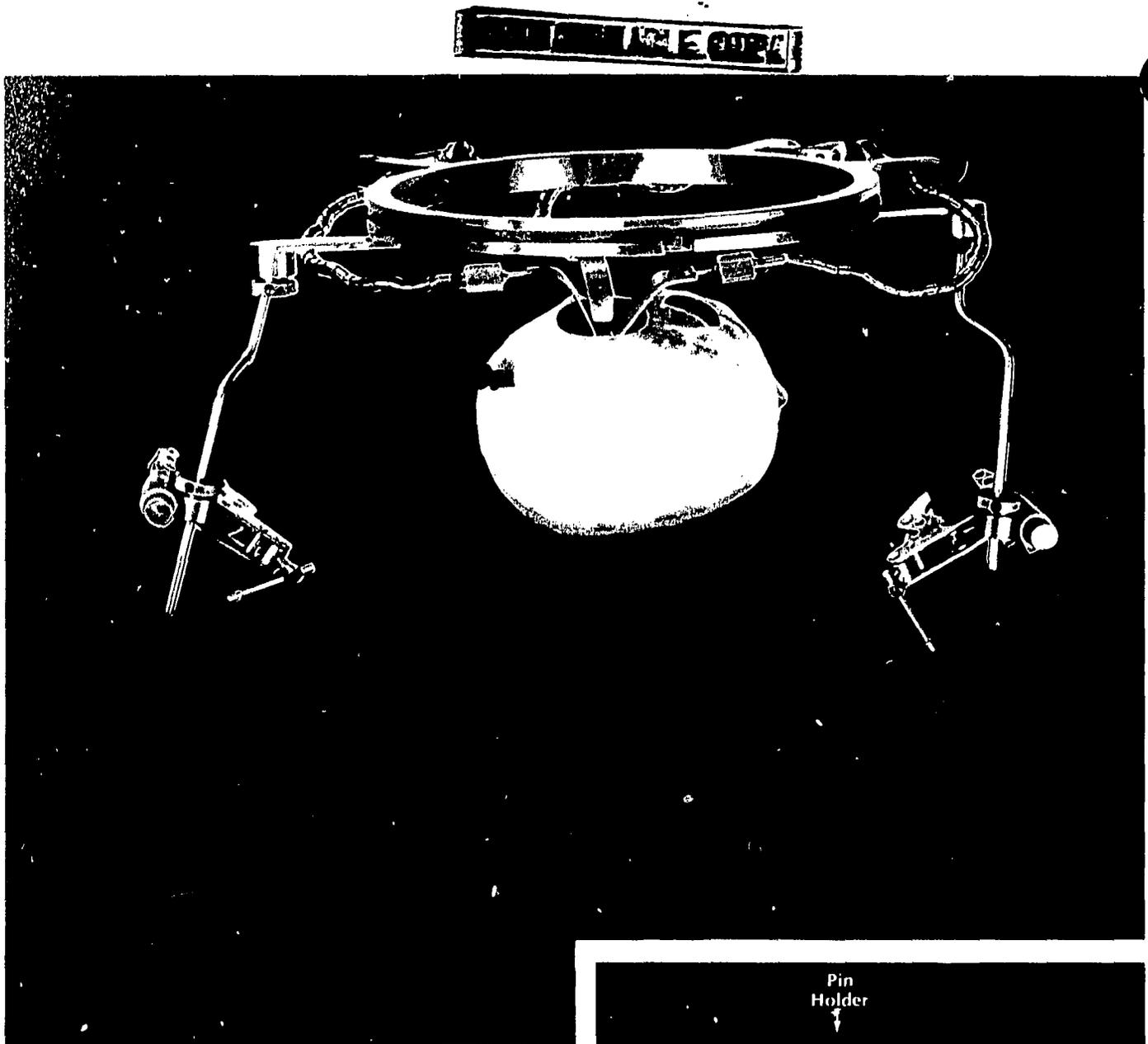
Cleaning

The unit should be taken apart and thoroughly scrubbed with a soft brush and mild detergent. All moving parts, that are permanently assembled, must be kept free of debris. The entire unit may be sterilized in the Autoclave, but it is important that all parts, especially all moving parts, be lubricated with a preservative after cleaning. Time, temperature, and pressure settings should be referred to sterilizer manufacturers instruction manual.

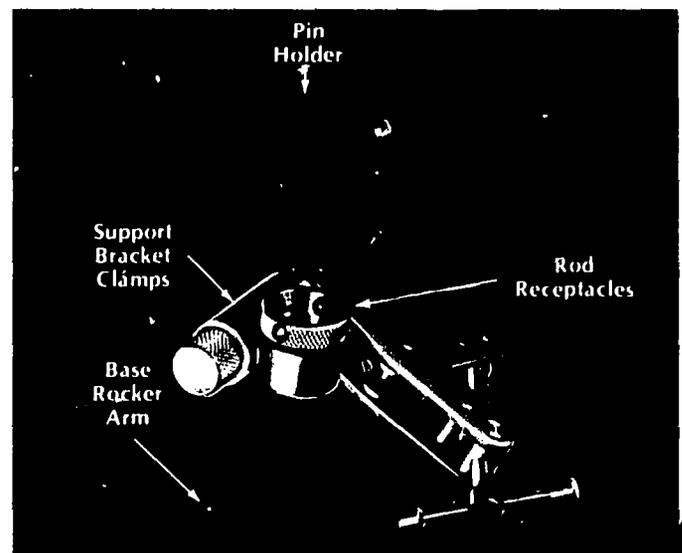
Warranty

Ohio Medical Instrument Company Inc. warrants for a period of one year from date of purchase that this instrument is free from defects in material and workmanship. An instrument or component found to be defective will either be replaced or repaired at our discretion. This item is listed and produced under F.D.A. Regulations governing good Manufacturing practices.

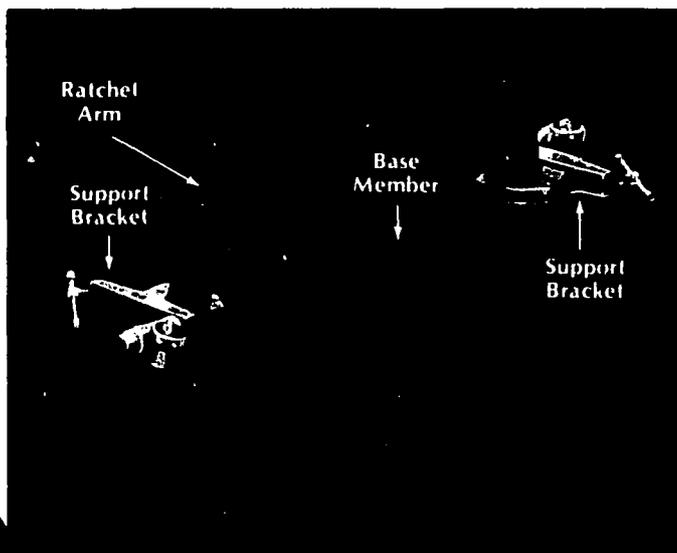
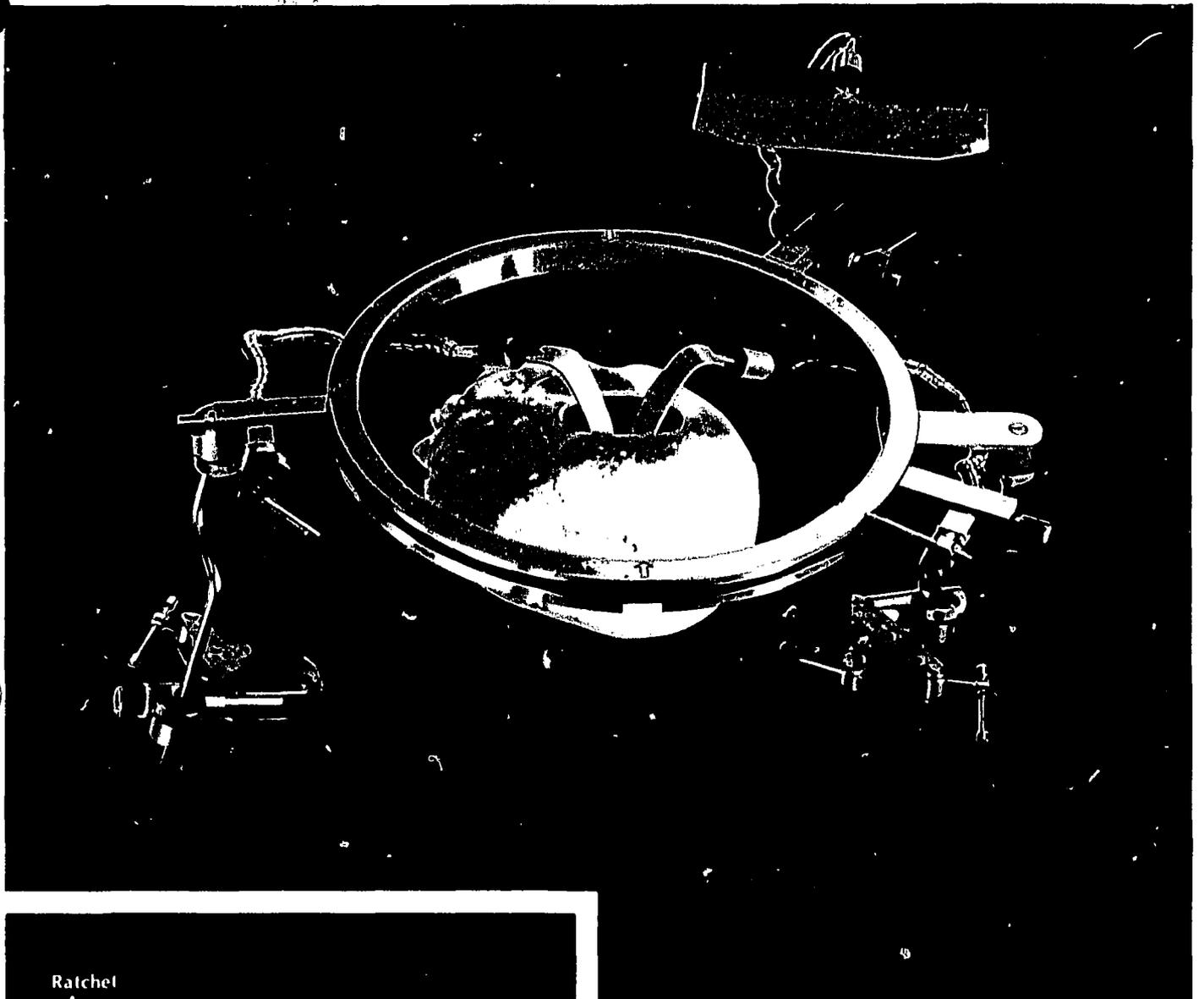
Patent Pending



Attachment to the Parkinson Headrest is made by first locating the two side knobs on the base of the rocker arm. The support bracket clamps will fit just above these knobs and below the pin holder assemblies. Both rod receptacles should be turned towards the center of the unit.

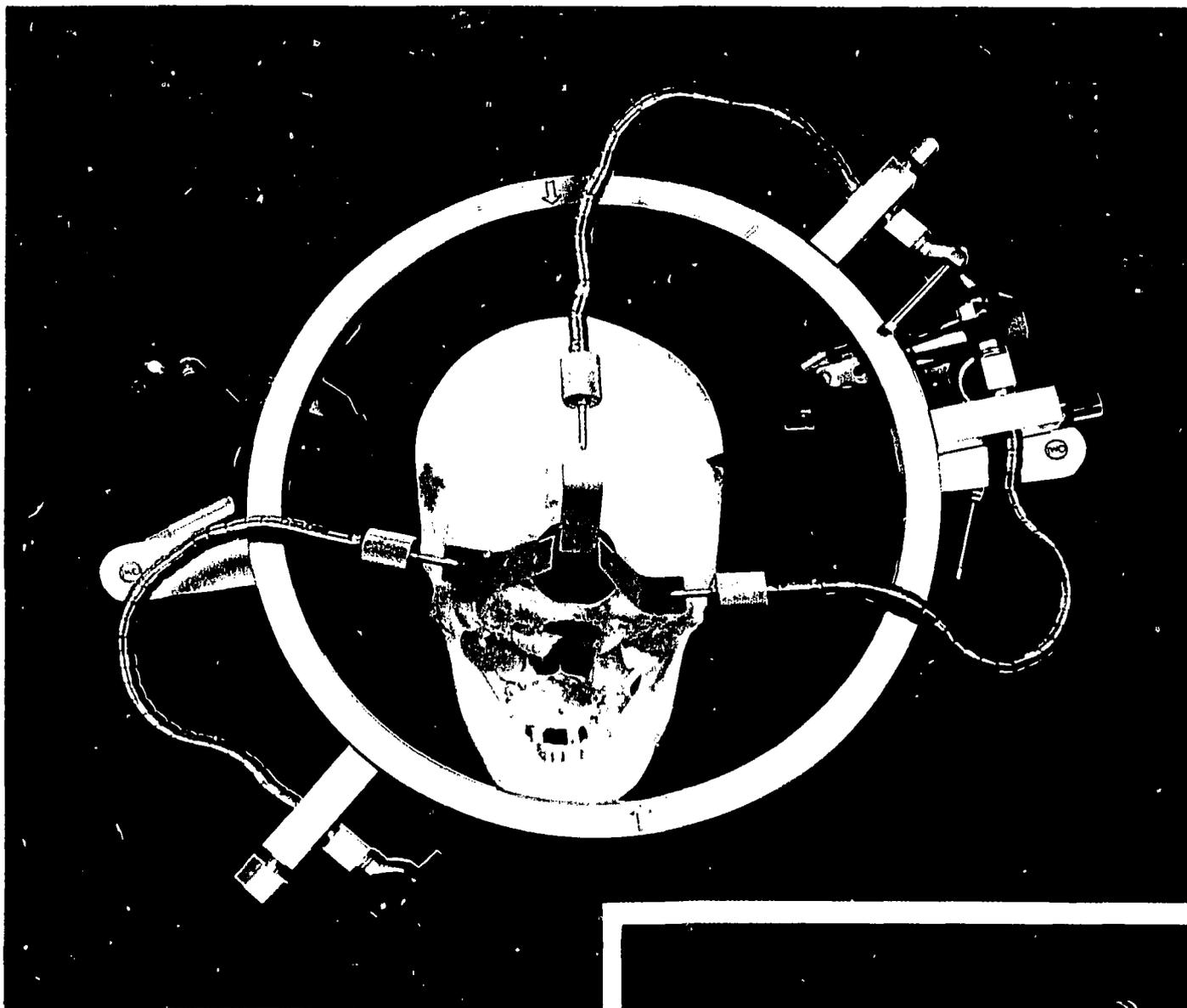


BEST AVAILABLE COPY

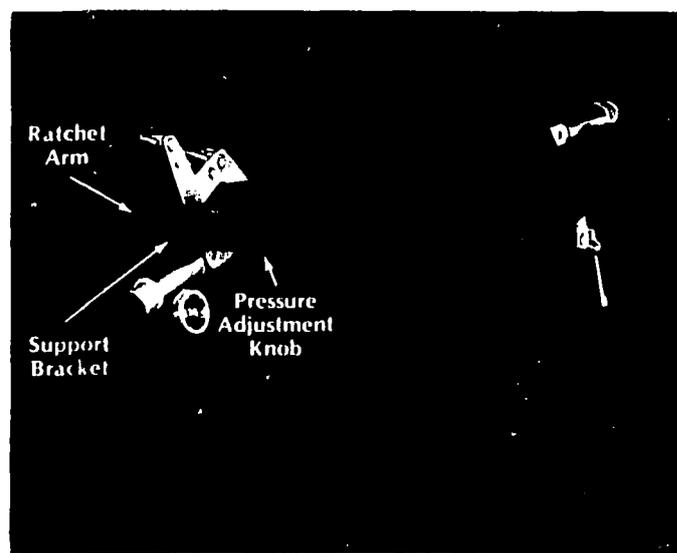


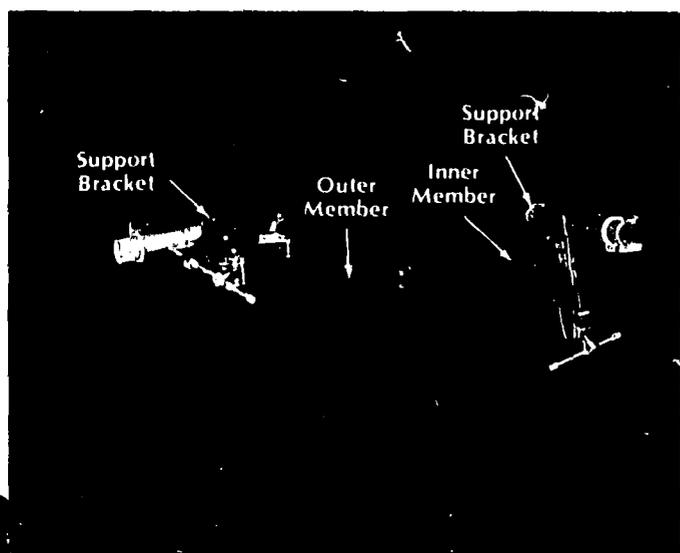
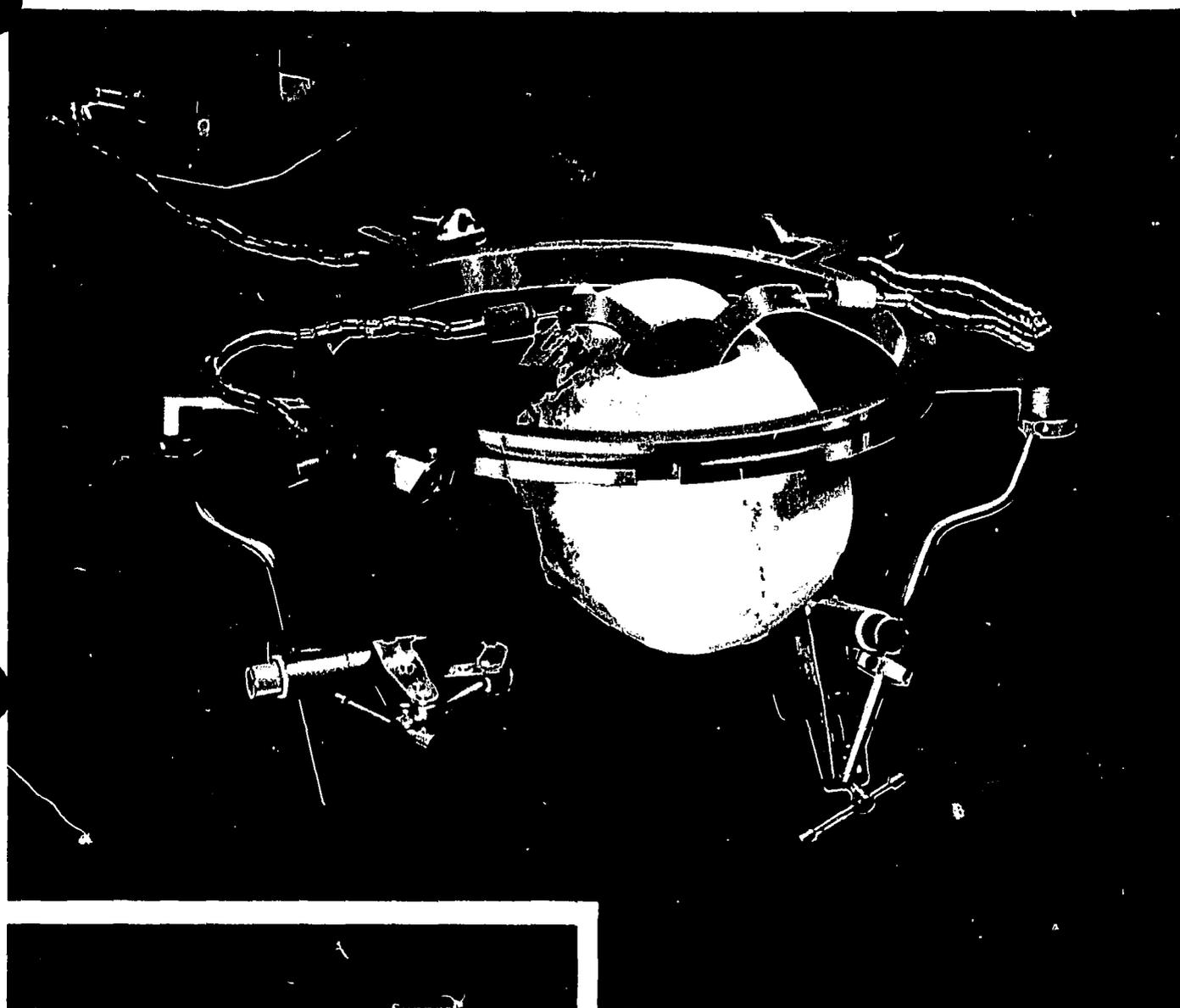
Attachment to the Mayfield (Standard) Skull Clamp with the original style Ratchet Arm is made by clamping one support bracket at the elbow of the Ratchet Arm with the support rod receptacle turned to the outside. The other clamp should be attached to the base member of the Skull Clamp just below the rocker arm, again with the support rod receptacle turned to the outside.

BEST AVAILABLE COPY



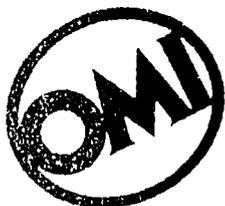
Attachment to the Mayfield (Modified Mayfield) Skull Clamp with the new wider Ratchet Arm member is made by clamping one support bracket just below the pressure adjustment knob of the Ratchet Arm with the support rod receptacle turned to the outside. The other clamp should be attached to the base member of the Skull Clamp just below the rocker arm, again with the support rod receptacle turned to the outside.





Attachment to the Gardner Skull Clamp is made by clamping one support bracket to the 1" square portion of the inner member. This should be located as close to the 1/4" thick single pin holding arm as is possible. The support rod receptacle should be turned towards the outside as shown. Attachment of the support bracket to the outer member is made on the arm holding the double pins and should be placed at the bottom of this arm to avoid interference with the rocker arm. The support rod receptacle must be turned towards the operating table as shown.

BEST AVAILABLE COPY



Ohio Medical Instrument Company, Inc.
Cincinnati, Ohio U.S.A.
Questions? CONTACT FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BUDE-HALO
RETRACTOR

ETCHED IN
STILLS, STL, C

[redacted]
STICKER

BEST AVAILABLE COPY

EXHIBIT II
PRE-MARKET APPRO

BUDDE-HALO
RETRACTOR

ETCHED IN
STILLS, STL, CASE

STICKER

EXHIBIT II
PRE-MARKET APPROVAL

The Greenberg Retractor and Handrest, A Universal System*

Instruction Manual

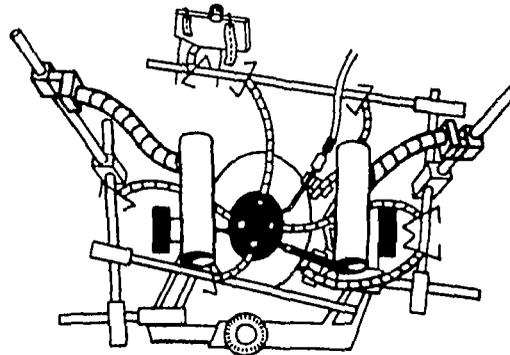


EXHIBIT III
PRE-MARKET APPROVAL
OHIO MEDICAL INSTRUMENT CO.

Codman

*Trademark of I.M. Greenberg, M.D.

BEST AVAILABLE COPY

Introduction

by I. M. Greenberg, M.D.

Since its introduction in 1975, the Greenberg Retractor and Handrest System has been most frequently used in conjunction with the Gardner Headrest as a support base. Many surgeons, however, prefer to use the Mayfield Headrest because of its mechanical advantages. Because the literature to date has demonstrated only the procedures required when using the Gardner Headrest with the Greenberg System, there is a need to describe how the Greenberg System can be used with the Mayfield Headrest.

The Greenberg System is a set of instruments which surround the operative site. First are a pair of 6-inch long, steel Primary Bars, 1/2-inch in diameter, with clamps for attachment to the Headrest. Longer Secondary Bars (12 inches) are then clamped to either the Primary Bars or to each other. FLEXBAR Retractor Arms are attached to these Secondary Bars and serve to support and position various instruments, including handrests, retractor blades, suctioning devices, dissectors, scissors or drills. Most recently the increasingly-sophisticated manner in which this system is used has led to the practice of conceptualizing three progressively-higher levels of instruments, based upon function. Level I is retraction, Level II is hand resting, and Level III is dynamic instrument support.

BEST AVAILABLE COPY

BEST AVAILABLE COPY

EQUIPMENT LIST

Gardner

2 ea., 50-1507, Greenberg Primary Bar
5 ea., 50-1508, Greenberg Secondary Bar
7 ea., 50-1509, Greenberg Retractor Arm*
4 for Retraction
2 for Instruments
1 for Paddle Tray
2 ea., 50-1515, Greenberg Maxi-Vise

2 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1512, Greenberg Handrest

1 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1509, Greenberg Retractor Arm
1 ea., Greenberg Maxi-Vise, Lg.
1 ea., 50-1515, Greenberg Maxi-Vise

LEVEL I

Mayfield

2 ea., 50-1507, Greenberg Primary Bar
4 ea., 50-1508, Greenberg Secondary Bar
7 ea., 50-1509, Greenberg Retractor Arm
4 for Retraction
2 for Instruments
1 for Paddle Tray
2 ea., 50-1515, Greenberg Maxi-Vise

**LEVEL II
(Add to Level I)**

2 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1512, Greenberg Handrest

**LEVEL III
(Add to Level II)**

1 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1509, Greenberg Retractor Arm
1 ea., Greenberg Maxi-Vise, Lg.
1 ea., 50-1515, Greenberg Maxi-Vise

*Greenberg Retractor Arm also available in 6½" (165mm) size (50-1511)

REFERENCES

1. Greenberg, I.M.: "Self-Retaining Retractor and Handrest System for Neurosurgery," NEURO-SURGERY 8:205-208, 1981
2. Greenberg, I.M.: "New Options for Microsurgeon, Multiple Instrumentation in a Single Microsurgical Field," NEURO-SURGERY 9:566, 1981
3. Greenberg, I.M.: "Staircase Concept of Instrument Placement in Microsurgery," NEURO-SURGERY 9:696-702, 1981

FLEXBAR Adjustments

The FLEXBAR flexible arm, which provides a wide range of positions for the retractor blades, hand-rests, and instruments, must be used correctly to maximize its life. Follow these simple rules:

1. When making major adjustments in the positioning of the FLEXBAR, loosen the knob until the FLEXBAR becomes limp, reposition, and then tighten.
2. When making minor adjustments in the positioning of the FLEXBAR, loosen the adjustment knob slightly. Retighten knob after the adjustment has been made.
3. Once blades are set in the depth of the field and subtle movements are needed, no change in tension is necessary and no readjustment of the knob need be done.

CAUTION: Forcing the FLEXBAR to move against its preset tension will cause the cable in the FLEXBAR to wear and possibly to break. The ball joints will also become scored and the FLEXBAR will tend to drift.

After a period of time, there may be drifting in the handrest even though the FLEXBAR knob is made tight. This is usually due to the drawbar threads becoming worn and this part (drawbar) may have to be replaced.

CLEANING

Disassemble and scrub the instruments and parts thoroughly using a soft brush and a mild detergent. Remove all traces of blood and debris. Make sure all moveable parts are cleaned thoroughly to prevent debris from interfering with movement. It is recommended that the instruments and parts be ultrasonically cleaned.

LUBRICATION

It is extremely important that moveable parts be properly lubricated to keep these parts functional. It is recommended that all components be immersed in a water-soluble lubricant. PRESERVE* Concentrate (catalog no. 43-1033) is recommended for instruments to be steam sterilized.

STERILIZATION

The instruments may be steam or gas sterilized. Refer to the sterilizer manufacturer's instructions for correct time, temperature and pressure settings.

WARRANTY

Codman & Shurtleff, Inc., warrants that the instruments are free from defects in both material and workmanship. Suitability for use of the instruments for any surgical procedure shall be determined by the user. Codman shall not be liable for incidental or consequential damages of any kind. The above warranties are in lieu of all other warranties either expressed or implied, including any warranty of any merchantability or fitness for use.

SERVICE AND REPAIR

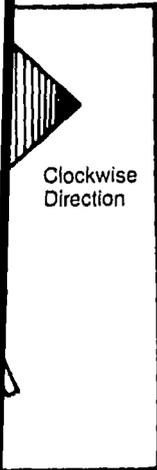
Send all instruments for service or repair to:

Codman Repair Service
Codman & Shurtleff, Inc.
Randolph Industrial Park
Randolph, MA 02368

Always include the purchase order number and a written description of the problem.

Control knob

(Flexbar
age) to the
of Flexbars



Flexbar and
nger or stiffer.

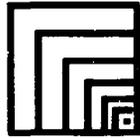
*Trademark

BEST AVAILABLE COPY

estimates? Contact DAACDR-HOCFAD at CDR-HOISATI@daahs.dau.af.mil-706-8

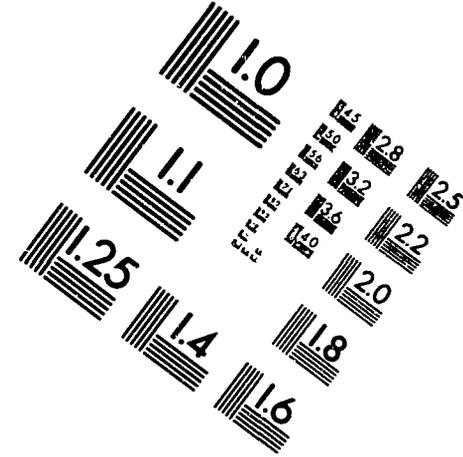
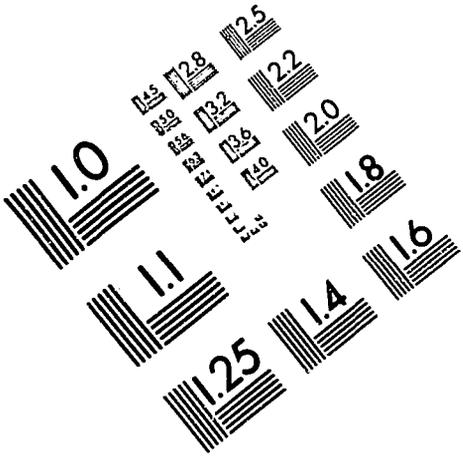
K 8 3 0 3 3 2

84

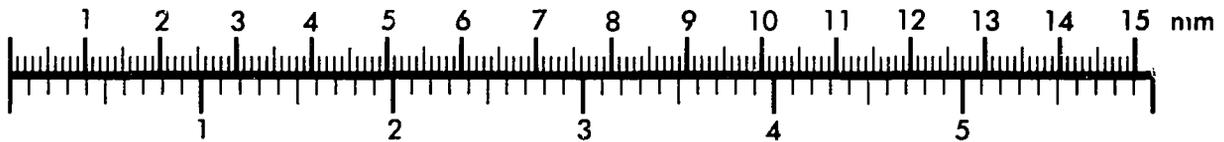


**NATIONAL
MICROGRAPHICS
ASSOCIATION**

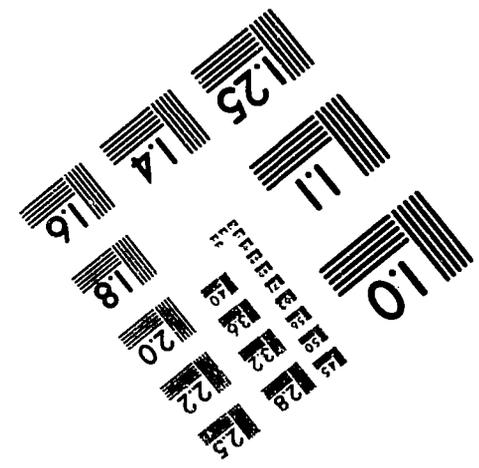
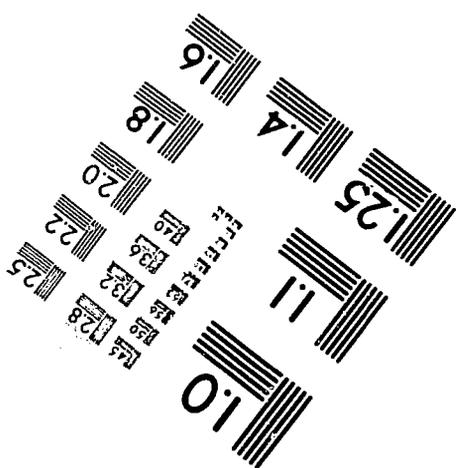
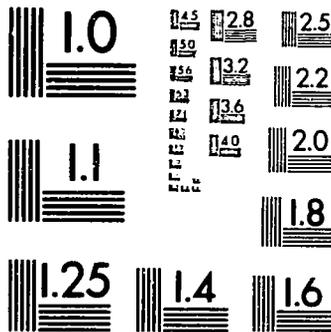
MS303-1980



Centimeter



Inches



K830332



MAR 2 1983

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Chris G. Klahm
Engineering Coordinator
for FDA Compliance
Ohio Medical Instrument Company, Inc.
315 West Liberty
Cincinnati, Ohio 45214

Ref: K830332 - Budde-Halo Retractor

Dated: January 24, 1983
Received: February 1, 1983
Regulatory class: II

Dear Mr. Klahm:

We have reviewed your premarket notification submission and have found the device to be substantially equivalent to devices introduced into 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). This product has been placed into the regulatory class shown above by a final regulation published in the Federal Register. Class I devices are regulated by the general control provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices are those for which future performance standards will be developed; class III devices are those which will be required to undergo premarket approval at some time in the future.

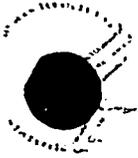
Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Section 800. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently 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. 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 need further assistance on the labeling for your device, please contact the Office of Medical Devices, Division of Compliance Operations (HFK-110), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

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

DISCONTINUED COPY



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date 2/28/83
 From Reviewer(s) - Name(s) A Doyle Hunt
 Subject 510(K) Notification K830332
 To 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:

Class Code w/ Panel:

classification based on
882.4800
Self-Retaining Retractors for Neurosurgery

84GET

REVIEW: [Signature] 2/28/83
DATE

CONV. REVIEW: [Signature] 2/28/83
DATE
 DIVISION DIRECTOR

OPTIONAL REVIEW: _____
ASSOC. DIRECTOR FOR DEVICE EVAL. DATE

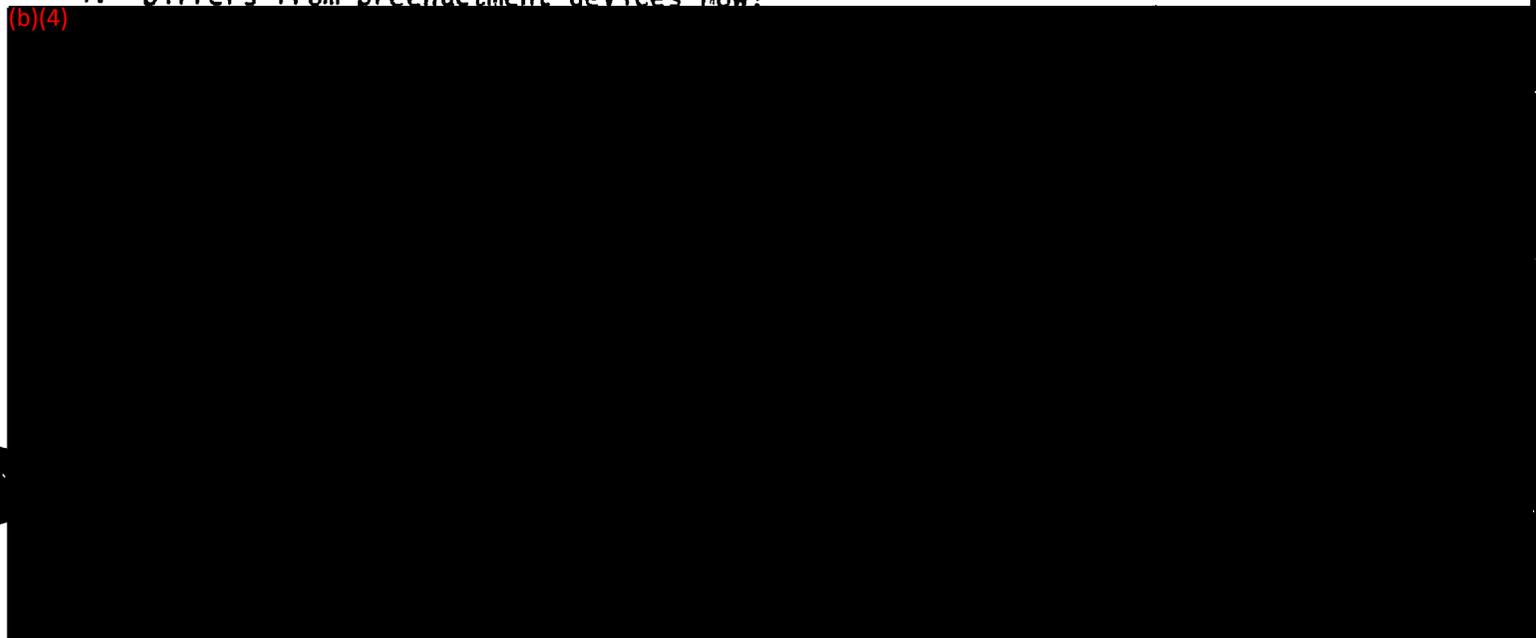
Company Name Ohio Medical Instrument Co, Inc. K830332

Device Name Budd - Halo Retractor

- | | | |
|--|---------------|---------------|
| | YES | NO |
| 1. Life-supporting or life-sustaining? | <u> </u> | <u> </u> |
| 2. Implant (short-term or long-term)? | <u> </u> | <u> ✓ </u> |

3. Similar preenactment device(s): Greenberg Retractor + Handrest
(device name, manufacturer)
Codman + Shurtleff

4. Differs from preenactment devices how?



5. If appropriate: provides comparative in vitro data: No
- provides a summary of animal testing? No
- provides a summary of clinical testing? No

6. I believe this is equivalent to device(s): # 94G2T
Classification should be based on:

Subsection Self-Retaining Retractors for Neurosurgery (presently Class II)
482.4800 (name)

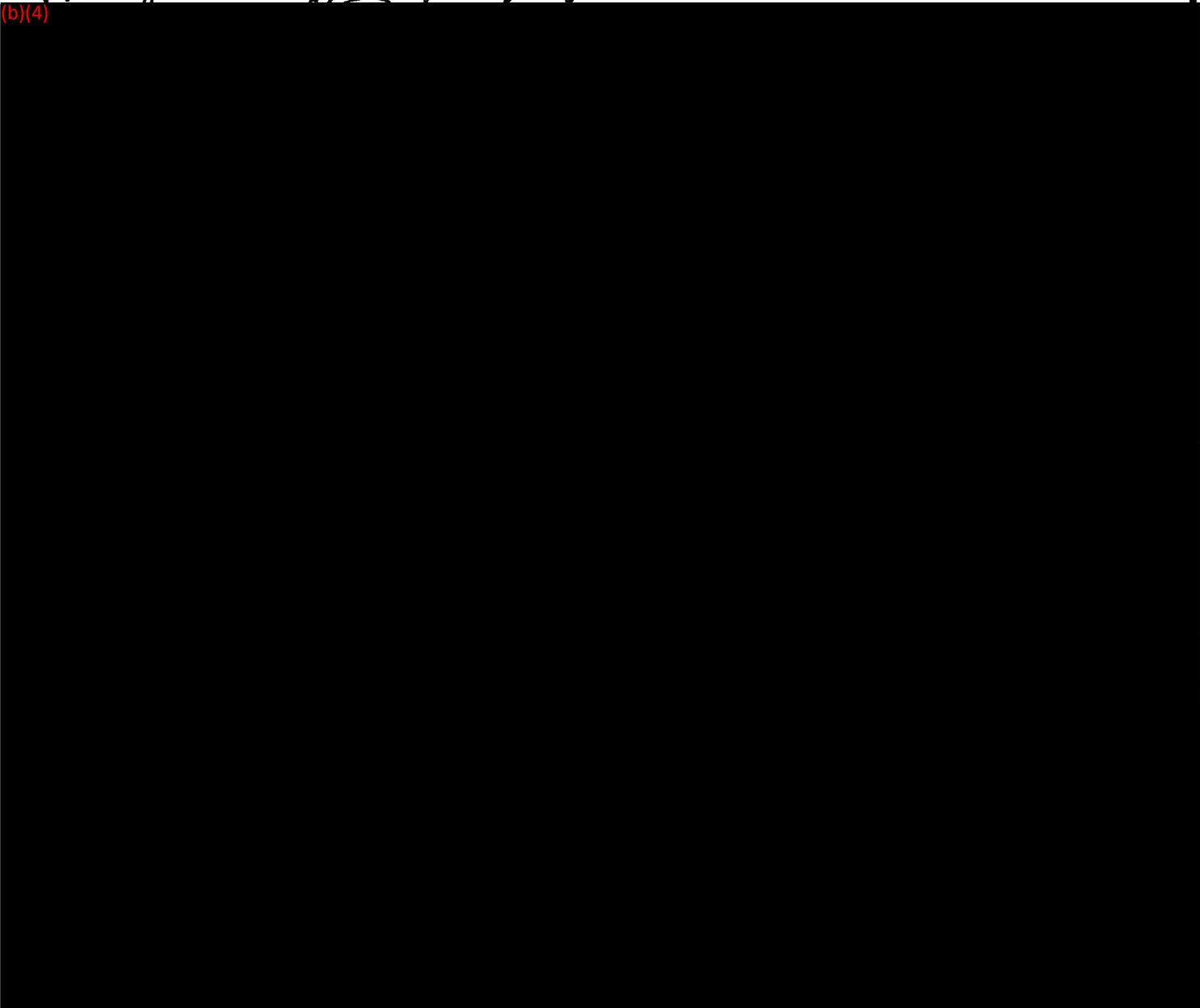
A D Gault 2/29/83
(sign & date)

I believe this is not equivalent to any preenactment device.

I believe clinical testing is required before a determination can be made.

BEST AVAILABLE COPY

MEMO RECORD		AVOID ERRORS PUT IT IN WRITING	DATE 2/23/83
FROM: Biomedical Engineer #FK430		OFFICE ADDE	
TO: K830332		DIVISION DAND	
SUBJECT: Memorandum of a Telephone Conversation			
SUMMARY I talked with Mr. Klahm today and discussed the following concerning his 510(k) for the			



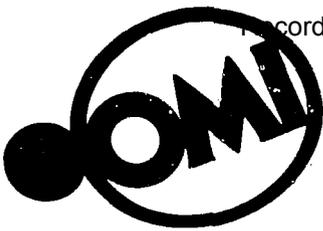
(b)(4)

cc: Gant II / Chron A. Doye Pitt

BEST AVAILABLE COPY

SIGNATURE	DOCUMENT NO.
-----------	--------------

Questions? Contact FDA/CDRH/OCE/DID at CDRH.EQ1STATUS@fda.hhs.gov or 301-796-8118



OHIO
MEDICAL
INSTRUMENT
COMPANY, INC. 315 WEST LIBERTY, CINCINNATI, OHIO 45214 513/579-1661

January 24, 1983

K830332

RECEIVED
JAN 27 1983

Document Control Center
Bureau of Medical Devices (HFK-20)
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

Ref: 510K Submission
BUDE-HALO RETRACTOR

Attention: Document Control Clerk

Gentlemen:

OHIO MEDICAL INSTRUMENT COMPANY, INC. is requesting marketing clearance for its Halo Retractor. The Premarket Notification information requested by 21CFR 807.87 is as follows:

- a) Classification Name: Self Retaining Retractor
for Neurosurgery
Common/Usual Name: Halo Retractor
Proprietary Name: Budde-Halo Retractor
- b) Establishment Registration No: 1525725
- c) Classification: 21 CFR 882.4800 (April 1, 1982)
states that Self-Retaining Retractors
for Neurosurgery are classified as a
Class II Device.
- d) Performance Standards: At this time, there are no applicable performance standards for this device (according to Section 514;1976 Medical Device Amendments). Of course, OMI, Inc. does adhere to the GENERAL CONTROLS sections of the Medical Device Amendments, particularly the GMP clause (Section 520(F)).

BEST AVAILABLE COPY

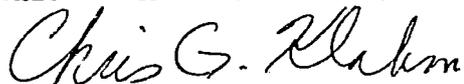
e) Label/Labeling/Advertisements: The enclosed Product Instruction Manual (See Exhibit I) will illustrate and describe the function of this product. The only other labeling utilized with the Halo Retractor is represented by the enclosed label facsimile (See Exhibit II). The words 'BUDE-HALO RETRACTOR' are etched by electrolysis on the carrying (sterilizing) case. The OMI sticker is attached just beneath the etching.

f) Substantial Equivalence: The Budde-Halo Retractor is similar in design, composition, and function to the GREENBURG RETRACTOR AND HAND-REST, marketed by CODMAN & SHURTLEFF, INC. (Randolph, Massachusetts). (See Exhibit III)

We would appreciate your earliest attention to this 510K submission, in order that we can obtain FDA compliance and offer this device for sale. If you need further information, please contact me at (513) 579-1661.

Cordially,

OHIO MEDICAL INSTRUMENT COMPANY, INC.



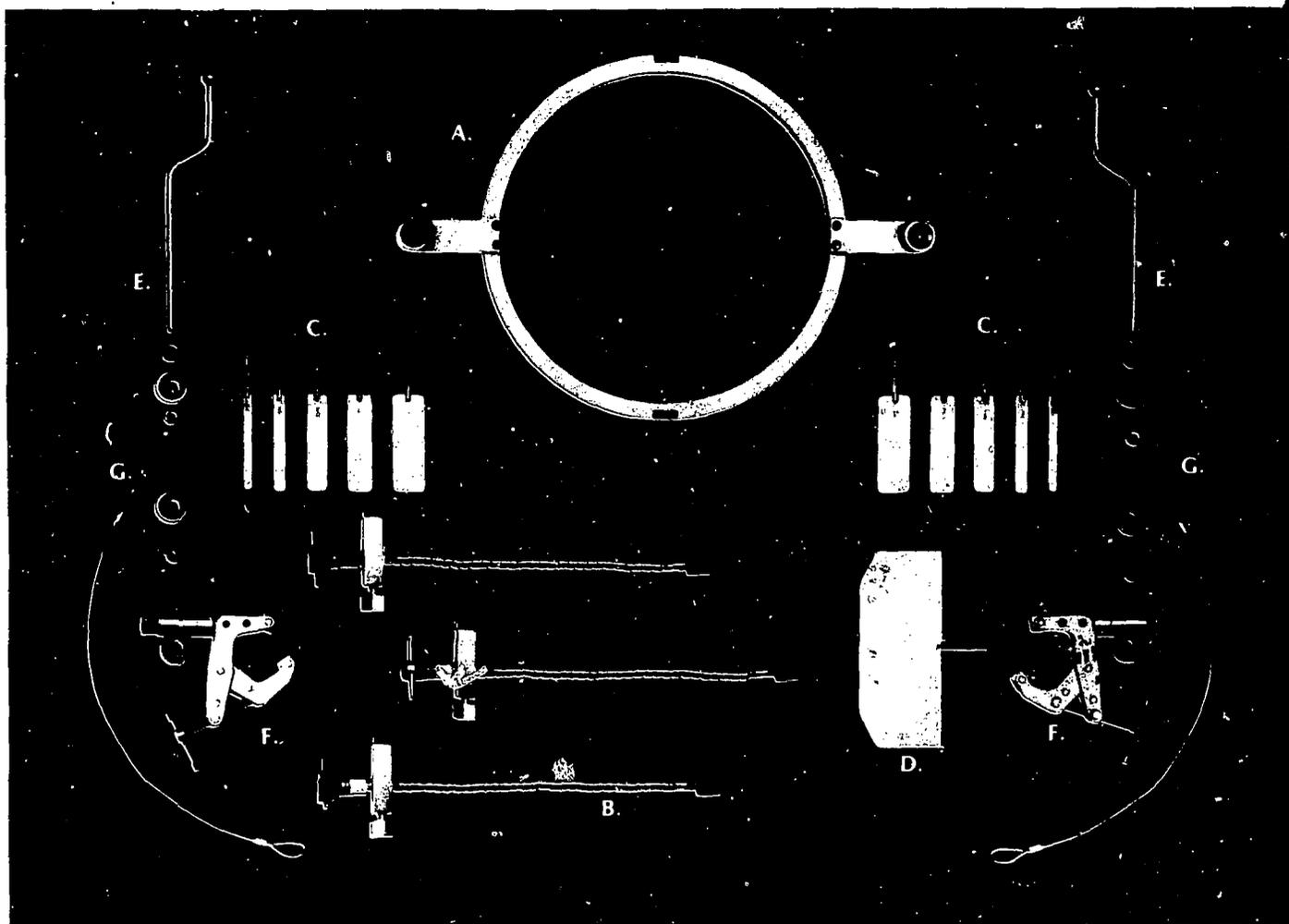
Chris G. Klahm
Engineering Coordinator for FDA Compliance

CGK/da

BEST AVAILABLE COPY

BLANK PAGE

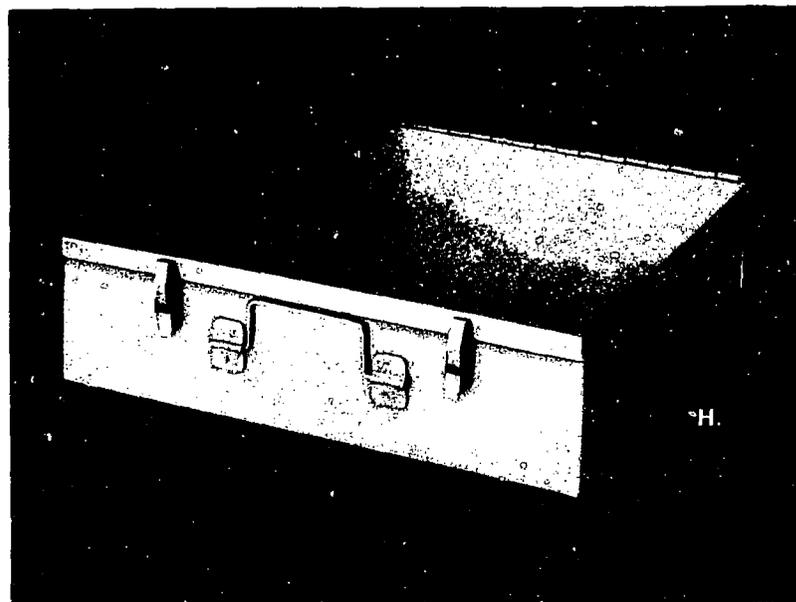
NOT AVAILABLE COPY



Retractor Kit A-1040 Includes

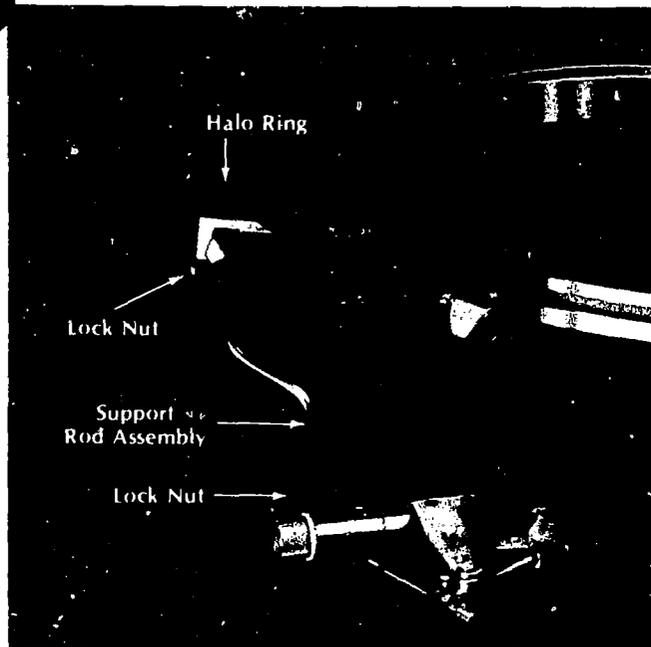
- A. (1) Halo Ring
- B. (3) 9" Retractor Arm
- C. (1) 4" Retractor Blade Kit*
- D. (1) Patty Tray
- E. (2) Support Rod Assembly
- F. (2) Support Bracket Assembly
- G. (2) Adjustment Wrench
- H. (1) Sterilizing Case

* Retractor Blade Kit consists of two each 1/4, 3/8, 5/8, 3/4, & 1"

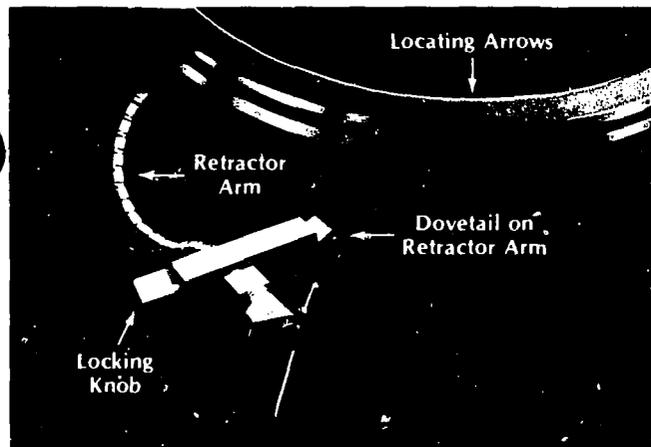


BEST AVAILABLE COPY

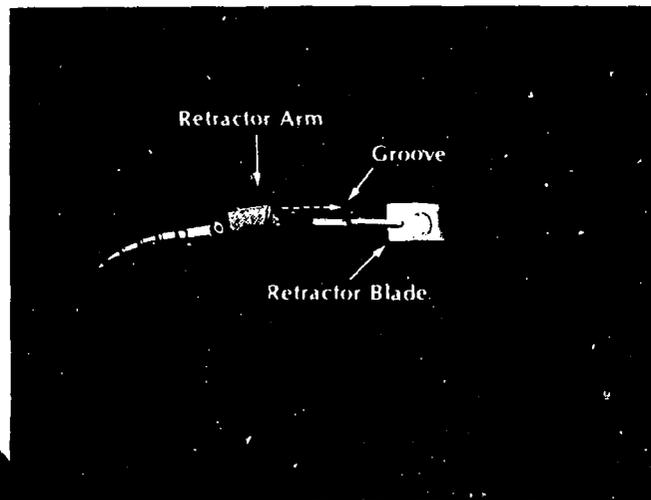
General Set Up Procedures



A. Attachment of the support rod assembly to the Halo Ring should be made with a hand tight fastening of the lock nuts. This will allow for movement of the balljoint when positioning the ring over the operating field. Loosen the locking nuts on the support brackets to allow the support rods to slide thru. Again hand tightening the locking nuts will allow for movement while still holding the Halo Ring in position. Adjust the ring to the desired location and secure all four lock nuts using the Lock Wrench.



B. Attachment of the Retractor Arms is accomplished by locating the openings directly under the arrows on either side of the ring and sliding the dovetail section of the Retractor Arm Bracket into the groove. After locating the desired number of arms in the position you wish, make sure each is securely locked using the knob on the end of the Retractor Arm Bracket.



C. The Retractor Blade Stems have a groove on one side which must line up with a centering dot that appears on the chuck of the Retractor Arm Assembly. By holding the Retractor Arm in your hand so as to be able to grasp the chuck with your thumb and forefinger, you will be able to push the chuck forward thus allowing the Retractor to be inserted. Removal of the Retractor requires the same technique.

Cleaning

The unit should be taken apart and thoroughly scrubbed with a soft brush and mild detergent. All moving parts, that are permanently assembled, must be kept free of debris. The entire unit may be sterilized in the Autoclave, but it is important that all parts, especially all moving parts, be lubricated with a preservative after cleaning. Time, temperature, and pressure settings should be referred to sterilizer manufacturers instruction manual.

Warranty

Ohio Medical Instrument Company Inc. warrants for a period of one year from date of purchase that this instrument is free from defects in material and workmanship. An instrument or component found to be defective will either be replaced or repaired at our discretion. This item is listed and produced under F.D.A. Regulations governing good Manufacturing practices.

Patent Pending



Ohio Medical Instrument Company, Inc.
Cincinnati, Ohio U.S.A.

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

BUDGE-HALO
RETRACTOR

ETCHED IN
STILLS, STL, C



STICKER

BEST AVAILABLE COPY

EXHIBIT II
PRE-MARKET APPRO

**BUDGE-HALO
RETRACTOR**

ETCHED IN
STILLS, STL, CASE

STICKER

EXHIBIT II
PRE-MARKET APPROVAL

The Greenberg Retractor and Handrest, A Universal System*

Instruction Manual

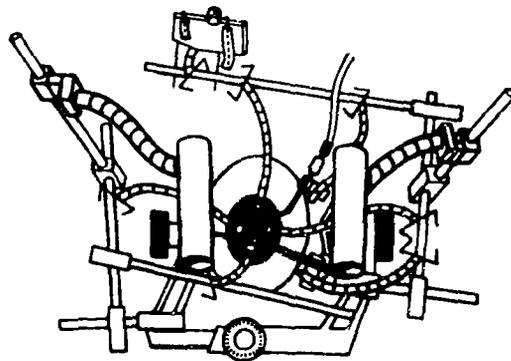


EXHIBIT III
PRE-MARKET APPROVAL
OHIO MEDICAL INSTRUMENT CO.

Codman

*Trademark of I.M. Greenberg, M.D.

BEST AVAILABLE COPY

Introduction

by I. M. Greenberg, M.D.

Since its introduction in 1975, the Greenberg Retractor and Handrest System has been most frequently used in conjunction with the Gardner Headrest as a support base. Many surgeons, however, prefer to use the Mayfield Headrest because of its mechanical advantages. Because the literature to date has demonstrated only the procedures required when using the Gardner Headrest with the Greenberg System, there is a need to describe how the Greenberg System can be used with the Mayfield Headrest.

The Greenberg System is a set of instruments which surround the operative site. First are a pair of 6-inch long, steel Primary Bars, 1/2-inch in diameter, with clamps for attachment to the Headrest. Longer Secondary Bars (12 inches) are then clamped to either the Primary Bars or to each other. FLEXBAR Retractor Arms are attached to these Secondary Bars and serve to support and position various instruments, including handrests, retractor blades, suctioning devices, dissectors, scissors or drills. Most recently the increasingly-sophisticated manner in which this system is used has led to the practice of conceptualizing three progressively-higher levels of instruments, based upon function. Level I is retraction, Level II is hand resting, and Level III is dynamic instrument support.

BEST AVAILABLE COPY

BEST AVAILABLE COPY

EQUIPMENT LIST

Gardner

2 ea., 50-1507, Greenberg Primary Bar
5 ea., 50-1508, Greenberg Secondary Bar
7 ea., 50-1509, Greenberg Retractor Arm*
4 for Retraction
2 for Instruments
1 for Pattie Tray
2 ea., 50-1515, Greenberg Maxi-Vise

2 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1512, Greenberg Handrest

1 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1509, Greenberg Retractor Arm
1 ea., Greenberg Maxi-Vise, Lg.
1 ea., 50-1515, Greenberg Maxi-Vise

LEVEL I

Mayfield

2 ea., 50-1507, Greenberg Primary Bar
4 ea., 50-1508, Greenberg Secondary Bar
7 ea., 50-1509, Greenberg Retractor Arm
4 for Retraction
2 for Instruments
1 for Pattie Tray
2 ea., 50-1515, Greenberg Maxi-Vise

**LEVEL II
(Add to Level I)**

2 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1512, Greenberg Handrest

**LEVEL III
(Add to Level II)**

1 ea., 50-1508, Greenberg Secondary Bar
2 ea., 50-1509, Greenberg Retractor Arm
1 ea., Greenberg Maxi-Vise, Lg.
1 ea., 50-1515, Greenberg Maxi-Vise

*Greenberg Retractor Arm also available in 6½" (165mm) size (50-1511)

REFERENCES

1. Greenberg, I.M.: "Self-Retaining Retractor and Handrest System for Neurosurgery," NEUROSURGERY 8:205-208, 1981
2. Greenberg, I.M.: "New Options for Microsurgeon, Multiple Instrumentation in a Single Microsurgical Field," NEUROSURGERY 9:566, 1981
3. Greenberg, I.M.: "Staircase Concept of Instrument Placement in Microsurgery," NEUROSURGERY 9:696-702, 1981

FLEXBAR Adjustments

The FLEXBAR flexible arm, which provides a wide range of positions for the retractor blades, hand-rests, and instruments, must be used correctly to maximize its life. Follow these simple rules:

1. When making major adjustments in the positioning of the FLEXBAR, loosen the knob until the FLEXBAR becomes limp, reposition, and then tighten.
2. When making minor adjustments in the positioning of the FLEXBAR, loosen the adjustment knob slightly. Retighten knob after the adjustment has been made.
3. Once blades are set in the depth of the field and subtle movements are needed, no change in tension is necessary and no readjustment of the knob need be done.

CAUTION: Forcing the FLEXBAR to move against its preset tension will cause the cable in the FLEXBAR to wear and possibly to break. The ball joints will also become scored and the FLEXBAR will tend to drift.

After a period of time, there may be drifting in the handrest even though the FLEXBAR knob is made tight. This is usually due to the drawbar threads becoming worn and this part (drawbar) may have to be replaced.

CLEANING

Disassemble and scrub the instruments and parts thoroughly using a soft brush and a mild detergent. Remove all traces of blood and debris. Make sure all moveable parts are cleaned thoroughly to prevent debris from interfering with movement. It is recommended that the instruments and parts be ultrasonically cleaned.

LUBRICATION

It is extremely important that moveable parts be properly lubricated to keep these parts functional. It is recommended that all components be immersed in a water-soluble lubricant. PRESERVE* Concentrate (catalog no. 43-1033) is recommended for instruments to be steam sterilized.

STERILIZATION

The instruments may be steam or gas sterilized. Refer to the sterilizer manufacturer's instructions for correct time, temperature and pressure settings.

WARRANTY

Codman & Shurtleff, Inc., warrants that the instruments are free from defects in both material and workmanship. Suitability for use of the instruments for any surgical procedure shall be determined by the user. Codman shall not be liable for incidental or consequential damages of any kind. The above warranties are in lieu of all other warranties either expressed or implied, including any warranty of any merchantability or fitness for use.

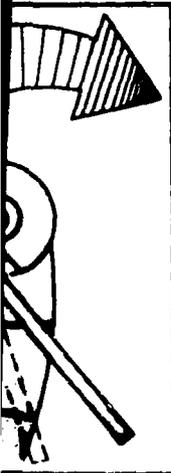
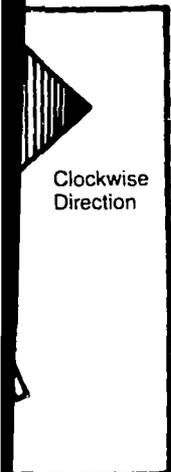
SERVICE AND REPAIR

Send all instruments for service or repair to:

Codman Repair Service
Codman & Shurtleff, Inc.
Randolph Industrial Park
Randolph, MA 02368

Always include the purchase order number and a written description of the problem.

control knob
y (Flexbar
age) to the
of Flexbars

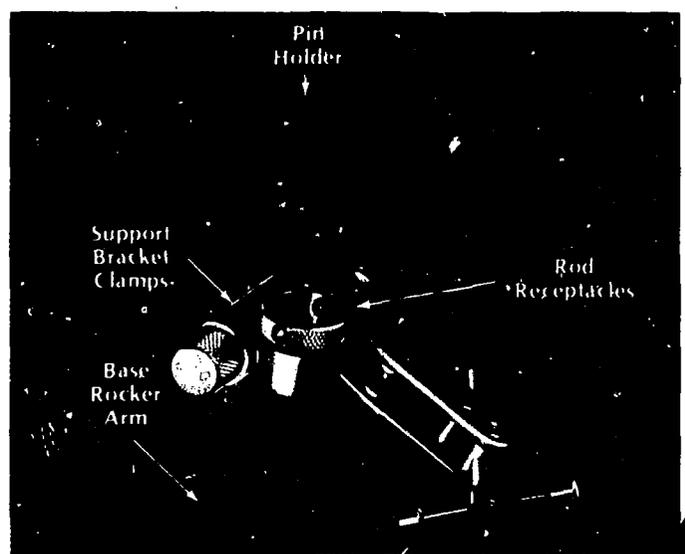


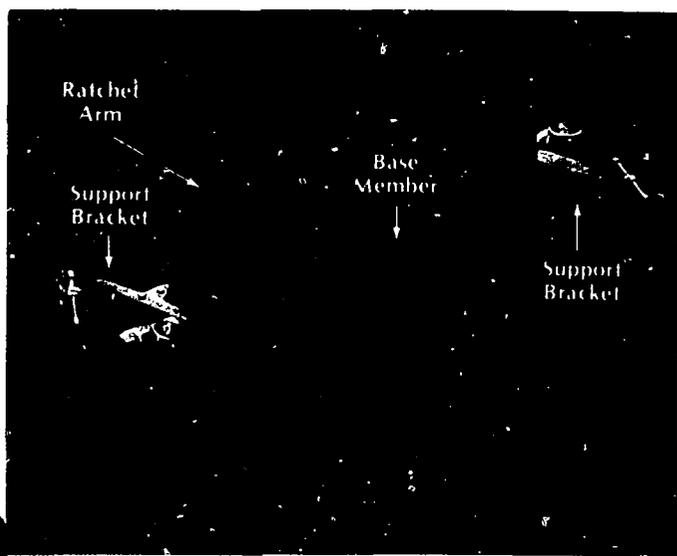
Flexbar and
ger or stiffer.

*Trademark

BEST AVAILABLE COPY

Attachment to the Parkinson Headrest is made by first locating the two side knobs on the base of the rocker arm. The support bracket clamps will fit just above these knobs and below the pin holder assemblies. Both rod receptacles should be turned towards the center of the unit.



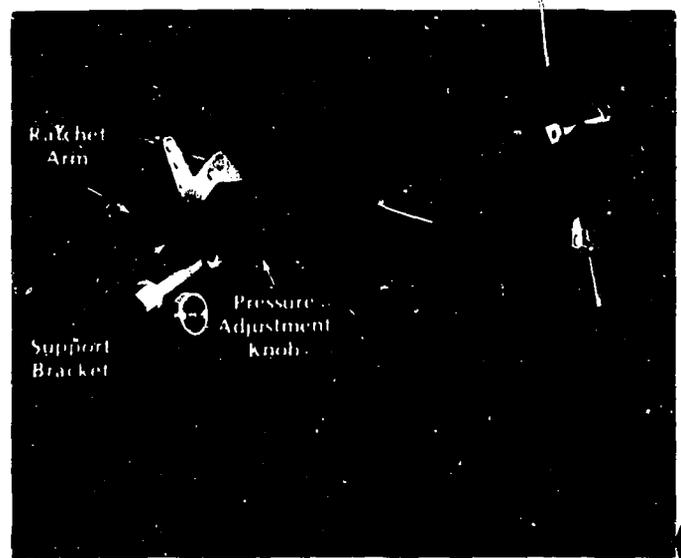


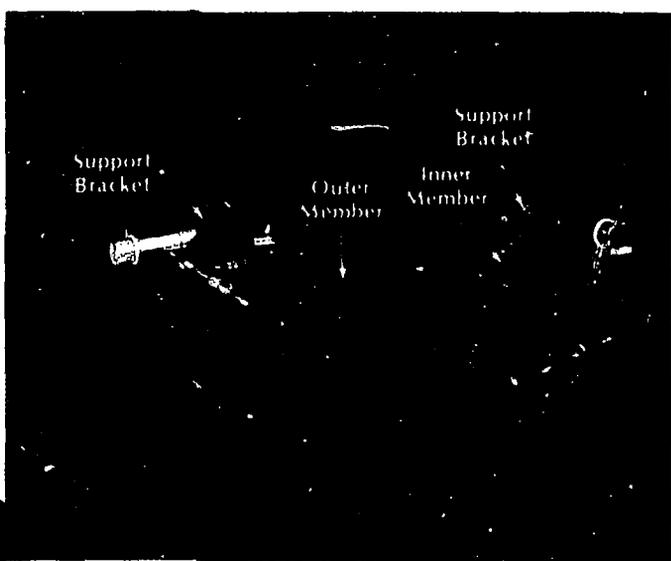
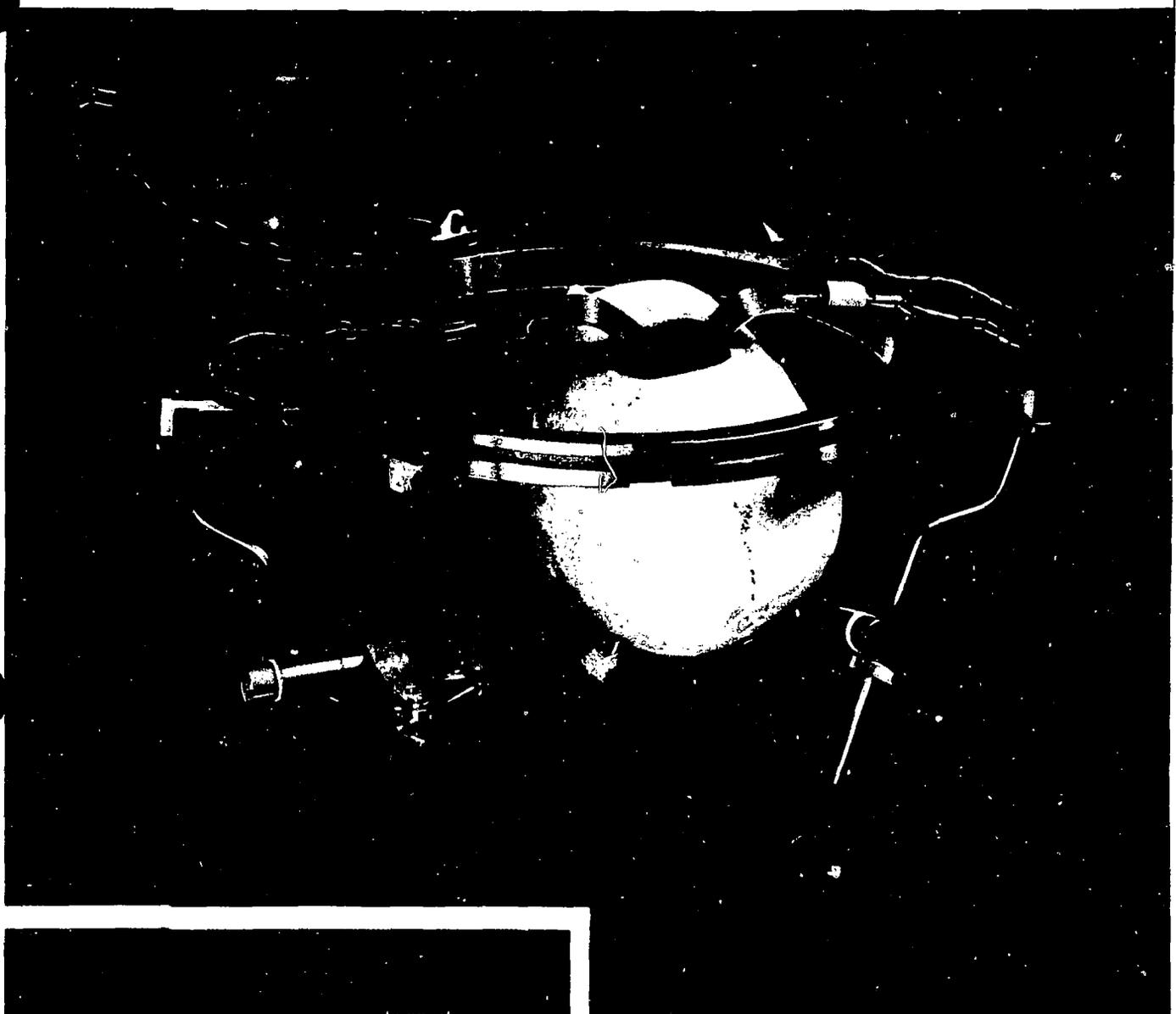
Attachment to the Mayfield (Standard) Skull Clamp with the original style Ratchet Arm is made by clamping one support bracket at the elbow of the Ratchet Arm with the support rod receptacle turned to the outside. The other clamp should be attached to the base member of the Skull Clamp just below the rocker arm, again with the support rod receptacle turned to the outside.

BEST AVAILABLE COPY



Attachment to the Mayfield (Modified Mayfield) Skull Clamp with the new wider Ratchet Arm member is made by clamping one support bracket just below the pressure adjustment knob of the Ratchet Arm with the support rod receptacle turned to the outside. The other clamp should be attached to the base member of the Skull Clamp just below the rocker arm, again with the support rod receptacle turned to the outside.





Attachment to the Gardner Skull Clamp is made by clamping one support bracket to the 1" square portion of the inner member. This should be located as close to the 1/4" thick single pin holding arm as is possible. The support rod receptacle should be turned towards the outside as shown. Attachment of the support bracket to the outer member is made on the arm holding the double pins and should be placed at the bottom of this arm to avoid interference with the rocker arm. The support rod receptacle must be turned towards the operating table as shown.

BEST AVAILABLE COPY