Summary of Safety and Effectiveness:

I. General Information

Classification:	Class II
Common Name:	Bipolar Forceps
Device Trade Name:	Titanium Bipolar Forceps BFT
Intended Uses:	Accessories to electrosurgical coagulation device, used to remove tissue and control bleeding by use of high frequency electrical current.
Predicate Device:	Various styles and models of: Kirwan Bipolar Forceps, Codman Bipolar Forceps and Valleylab Bipolar Forceps
Establishment Name and Address:	Radionics, Inc. P.O. Box 438, 22 Terry Ave. Burlington, MA 01803
Contact Name and Phone:	Linda Jalbert, (617) 272-1233
Establishment registration number:	1219140
Performance Standard:	None established under Section 514 of the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information supporting the Substantial Equivalence Determination.

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

General Safety and Effectiveness Concerns

RADIONICS BFT Titanium Bipolar Forceps labeling contains instructions for the proper use of these accessories. It includes a description of the products, directions for use, and applicable safety information. These instructions ensure safe and effective use of the devices when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The Titanium Bipolar Forceps accessories addressed in this premarket notification have the same intended use and technological characteristics as the commercially available Kirwan, Codman and Valleylab Bipolar Forceps. Like the Kirwan, Codman and Valleylab Bipolar Forceps, RADIONICS Bipolar Forceps are designed to be used with commercially available electrosurgical coagulation devices, to remove tissue and control bleeding by use of high frequency electrical current. Kirwan, Codman and Valleylab market various models of Titanium bipolar forceps. The RADIONICS Bipolar Forceps are offered in a variety of styles, lengths and tip configurations; the styles, lengths, and tip configurations are equivalent to forceps marketed by Kirwan, Codman and Valleylab.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

APR 21 1994

Ms. Linda Jalbert
Manager, Regulatory Affairs
Radionics, Inc.
P.O. Box 438
22 Terry Avenue
Burlington, Massachusetts 01803-2591

Re: K940466
Titanium Bipolar Forceps
Regulatory Class: II
Dated: April 6, 1994
Received: April 8, 1994

Dear Ms. Jalbert:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being

approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

8

510(K) ROUTE SLIP

510(k) NUMBER K940466 PANEL SU DIVISION DGRD BRANCH

TRADE NAME TITANIUM BIPOLAR FORCEPS

COMMON NAME BIPOLAR FORCEPS

PRODUCT CODE ___

APPLICANT RADIONICS, INC.
SHORT NAME RADIONICS
CONTACT LINDA JALBERT
DIVISION
ADDRESS P.O. BOX 438
22 TERRY AVENUE
BURLINGTON, MA 018032591
PHONE NO. (617) 272-1233 FAX NO. (617) 272-2428

MANUFACTURER RADIONICS, INC. REGISTRATION NO.

DATE ON SUBMISSION 29-JAN-94 DATE DUE TO 510(K) STAFF 18-APR-94

DATE RECEIVED IN ODE 02-FEB-94 DATE DECISION DUE 03-MAY-94

DECISION __ DECISION DATE _____

DMC
On hold / by phone
3/15/94

Rec'd 3/8/94
assigned to Rick Wallgren 3/8/94

B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date

From REVIEWER(S) - NAME(S) R. WEIBLINGER

Subject 510(k) NOTIFICATION K940466/S1

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) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

_____ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

Class II 79 GEI

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: _____ GSDB 4/20/94
(BRANCH CHIEF) BRANCH CODE (DATE)

FINAL REVIEW: _____ 4 20 94
(DIVISION DIRECTOR) (DATE)

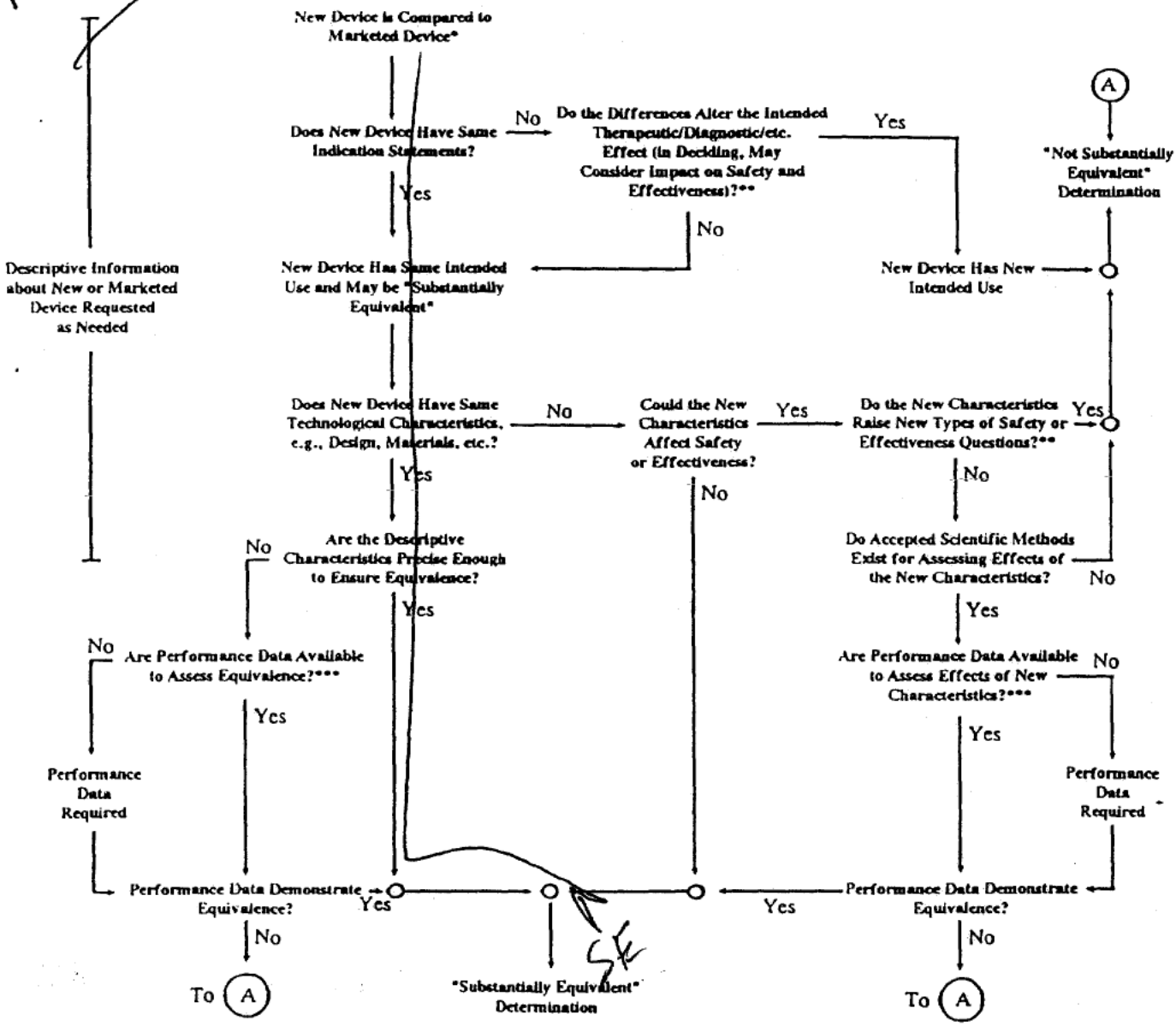
*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

4

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)

K940466



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

April 12, 1994

RADIONICS, INC.
P.O. BOX 438
22 TERRY AVENUE
BURLINGTON, MA 01803
ATTN: LINDA JALBERT

510(k) Number: K940466
Product: TITANIUM BIPOLAR FORCEPS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above 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.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

K 940466 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: R. WEIBLINGER DIVISION/BRANCH: DSRD/GIDB

TRADE NAME: _____ COMMON NAME: Freyja

PRODUCT TO WHICH COMPARED: Kinvara Inc. (Freyja) / Codman Inc. and Valleylab.
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DATA
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: forceps for electrosurgical procedures

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: see attached revision dated 3/14/94

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED:

1. EXPLAIN WHY NOT A DEVICE: is a device

2. EXPLAIN WHY NOT SUBJECT TO 510(k): is subject to 510(k)

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:
same indication.

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:
N/A

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:
N/A

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:
N/A

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

adequate.

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

N/A

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

N/A

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

N/A

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

N/A

ATTACH ADDITIONAL SUPPORTING INFORMATION

10

Revised: 8-20-93

Premarket Notification (510(k)) Checklist for Acceptance Decision

K 940466 Date DMC Received 2/2/94

Device Trade Name: Bipolar Forceps

Reason for 510(k) _____

Division/Branch: DGRD / 62DB

Administrative Reviewer Signature: _____ Date 3/14/94

Supervisory Signature: _____ Date 4/20/94

Did the firm request expedited review No

Did we grant expedited review No

accepted

refuse to accept

I. Critical Elements:	Yes Present Omission Justified	No Inadequate Omitted
A. Is the product a device?	☑	☐
B. Is the device exempt from 510(k) by regulation or policy?	☐	☑
C. Is device subject to review by CDRH?	☑	☐
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	☐	☑
E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer.	☐	☑
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	☐	☐

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	Yes Present Omission Justified	No Inadequate Omitted
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:		
1. Device trade or proprietary name	☑	☐
2. Device common or usual name or classification name	☑	☐
3. Establishment registration number (only applies if establishment is registered)	☑	☐
4. Class into which the device is classified under (21 CFR Parts 862 to 892)	☑	☐
5. Classification Panel	☑	☐
6. Action taken to comply with Section 514 of the Act	☐	☐
7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	☑	☐

G

	Yes Present Omission Justified	No Inadequate Omitted
8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	☑	☐
9. For class III devices only, a class III certification and a class III summary	☐	☐
10. Photographs of the device	☑	☐
11. Engineering drawings for the device with dimensions and tolerances	☐	☐
12. The marketed device(s) to which equivalence is claimed including labeling and description of thedevice	☑	☐
13. Statement of similarities and/or differences with marketed device(s)	☑	☐
14. Data to show consequences and effects of a modified device(s)	☐	☐
II. Additional Information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	☑	☐

	Yes Present Omission Justified	No Inadequate Omitted
B. Contact person, telephone number and fax number	☑	☐
C. Representative/Consultant if applicable	☑	☐
D. Table of Contents with pagination	☑	☐
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	☑	☐
III. Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	☑	☐
B. Action taken to comply with voluntary standards	☐	☐
C. Performance data		
marketed device		
bench testing	☐	☐
animal testing	☐	☐
clinical data	☐	☐

	Yes Present Omission Justified	No Inadequate Omitted
new device		
bench testing	☐	☐
animal testing	☐	☐
clinical data	☐	☐
D. Sterilization information	☐ N/A	☐
E. Software information	☐ N/A	☐
F. Hardware information	☐ N/A	☐
G. If this 510(k) is for a kit, has the kit certification statement been provided?	☐	☐
H. Is this device subject to issues that have been addressed in specific guidance document(s)?	☐	☐
If yes, continue review with checklist from any appropriate guidance documents.		
If no, is 510(k) sufficiently complete to allow substantive review?		

	Yes Present Omission Justified	N Inadequate Omitted
I. Other (specify)	☐	☐

3

Department of Health and Human Services **Public Health Service**
Food and Drug Administration

MEMORANDUM

From: R. Weiblinger, Biologist
ODE/DGRD/GSDB

Subject: K940466s
Forceps for Electrosurgical Procedures

To: Record

Review of K940466s1 Supplement

Submission date: 4/6/94
Received date: 4/8/94
Review date: 4/20/94

Sponsor: Radionics, Inc.
ATTN: Linda Jalbert
P.O. Box 438
22 Terry Avenue
Burlington, MA 01803-2591
617-272-1233

Device: Forceps for Electrosurgical Procedures (bipolar)

Category: *Class II*
Product code: 79 GEI (electro surgical)

Introduction:

The application is for varous sizes of electrosurgical forceps. The subject devices are intended to be used in electro-surgery. This submission is in response to request for additional information. See review dated 3/14/94 for detailed review.

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Device Description - deficiencies

Since these devices have electrosurgical capabilities the following information is needed:

a. The forceps must conform with ANSI/AAMI, HF-18, 1993 design standards for electrosurgical devices. Performance evaluation testing information may be provided to FDA.

Firms response dated 4/6/94:

The firm now certifies tha they are in compliance with AAMI electrosurgical standard HF-18.

b. a description of the types of electrosurgical generators that are compatible with these devices must be provided.

Firms response dated 4/6/94:

The firm notes that their devices are compatible with Radionics coagulators: 440 systems (pre-amendment), and CBC-1 systems (see K870149 and K871077).

Recommended Regulatory Action:

The firm was contacted by telephone on 2/14/94 and the above issues were discussed with the firm. The firm has now forwarded the requested information to FDA in a response dated 4/6/94. In addition, the submission was reviewed by Neurological Devices Branch/DCRND/ODE (G. Levering Keely). The DCRND reviewer concurs with an SE decision (see memorandum dated 4/19/94 attached). This application is now recommended to found SE.

Richard Paul Weiblinger

cc: RWeiblinger ODE/DGRD/GSDB
Gen Surg Div File

19

I N T E R O F F I C E M E M O R A N D U M

Date: 18-Apr-1994 04:38pm EDT
From: Richard P. Weiblinger
RPW
Dept: ODE-DOD
Tel No: 594-1307

TO: Robert F. Munzner (RFM)

CC: George C. Jan (GCJ)

Subject: Neurosurgical Consult

Bob,

Attached please find K940466. Please provide a neurological consult.

Thank you

Richard

Lev, This looks trivial, but I thought you should take a look to see if there might be some question.
Thanks.
4/18/94

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MEMORANDUM

DATE: April 19, 1994

FROM: G. Levering Keely, Neurological Devices Branch, HFZ-450
Office of Device Evaluation, DCRND

SUBJECT: K940466, Bipolar forceps

TO: Richard Weiblinger, ODE/DOD

I have reviewed the above 510(k) and find no significant differences between the product identified as the predicate device and that referenced in this 510(k). The BFT-20 through BFT-34 bipolar forceps are various designs of bipolar forceps with round or flat handles, a standard two pronged jack for connection to a generator. They are sterile multiple use devices with different lengths and angles for use with or without microscopic vision and are always used in neurosurgery. They are described in the narrative as having irrigation ports, however these are not shown in the pictures of the devices. This is not a problem since many irrigation forceps are currently available and the incorporation of such irrigation is an advantage since irrigation is needed with the use of these devices anyway.

I concur with the decision to find this device equivalent.

..... Levering Keely

21

RADIONICS, INC.

P.O. BOX 438, 76 CAMBRIDGE STREET, BURLINGTON, MASSACHUSETTS 01803-0738, U.S.A.
TELEPHONE: (617) 272-1233 – FAX: (617) 272-2428

April 6, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Subject: K940466, 510(k) for Titanium Bipolar Forceps

Dear ODE Staff:

This document provides the additional information requested by the Office of Device Evaluation.

Two copies are enclosed.

If you need any additional information, please call me at (617) 272-1233.

Sincerely yours,

RADIONICS, INC.

(b) (6)

Linda Jalbert
Manager, Regulatory Affairs

Attachment

22

The Bipolar Titanium Forceps are compatible with Radionics Coagulators:

440 Systems	Pre-Amendment
CBC-1 Systems	K870149 and K871077

The Radionics BFT series forceps are uninsulated forceps. Radionics certifies that the Titanium Bipolar Forceps (BFT Series) are in compliance with AAMI Electrosurgery Standard HF-18. No performance testing is required by this standard for uninsulated forceps; therefore no test reports are provided.

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

March 17, 1994

RADIONICS, INC.
P.O. BOX 438
22 TERRY AVENUE
BURLINGTON, MA 01803
ATTN: LINDA JALBERT

510(k) Number: K940466
Product: TITANIUM BIPOLAR FORCEPS

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

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a 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 your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

24

510(K) ROUTE SLIP

510(k) NUMBER K940466 PANEL SU DIVISION DGRD BRANCH

TRADE NAME TITANIUM BIPOLAR FORCEPS

COMMON NAME BIPOLAR FORCEPS

PRODUCT CODE ___

APPLICANT RADIONICS, INC.
SHORT NAME RADIONICS
CONTACT LINDA JALBERT
DIVISION
ADDRESS P.O. BOX 438
22 TERRY AVENUE
BURLINGTON, MA 018032591
PHONE NO. (617) 272-1233 FAX NO. (617) 272-2428

MANUFACTURER RADIONICS, INC. REGISTRATION NO.

DATE ON SUBMISSION 29-JAN-94 DATE DUE TO 510(K) STAFF 18-APR-94

DATE RECEIVED IN ODE 02-FEB-94 DATE DECISION DUE 03-MAY-94

DECISION __ DECISION DATE _____

CORRESPONDENCE	SENT	DUE BACK	
C001	15-MAR-94	14-APR-94	HOLD LETTER

25

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From REVIEWER(S) - NAME(S) R. WEIBLINGER

Subject 510(k) NOTIFICATION K940466

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) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☐

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

______ No Confidentiality

______ Confidentiality for 90 days

______ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

____

Additional Product Code(s) w/Panel (optional):

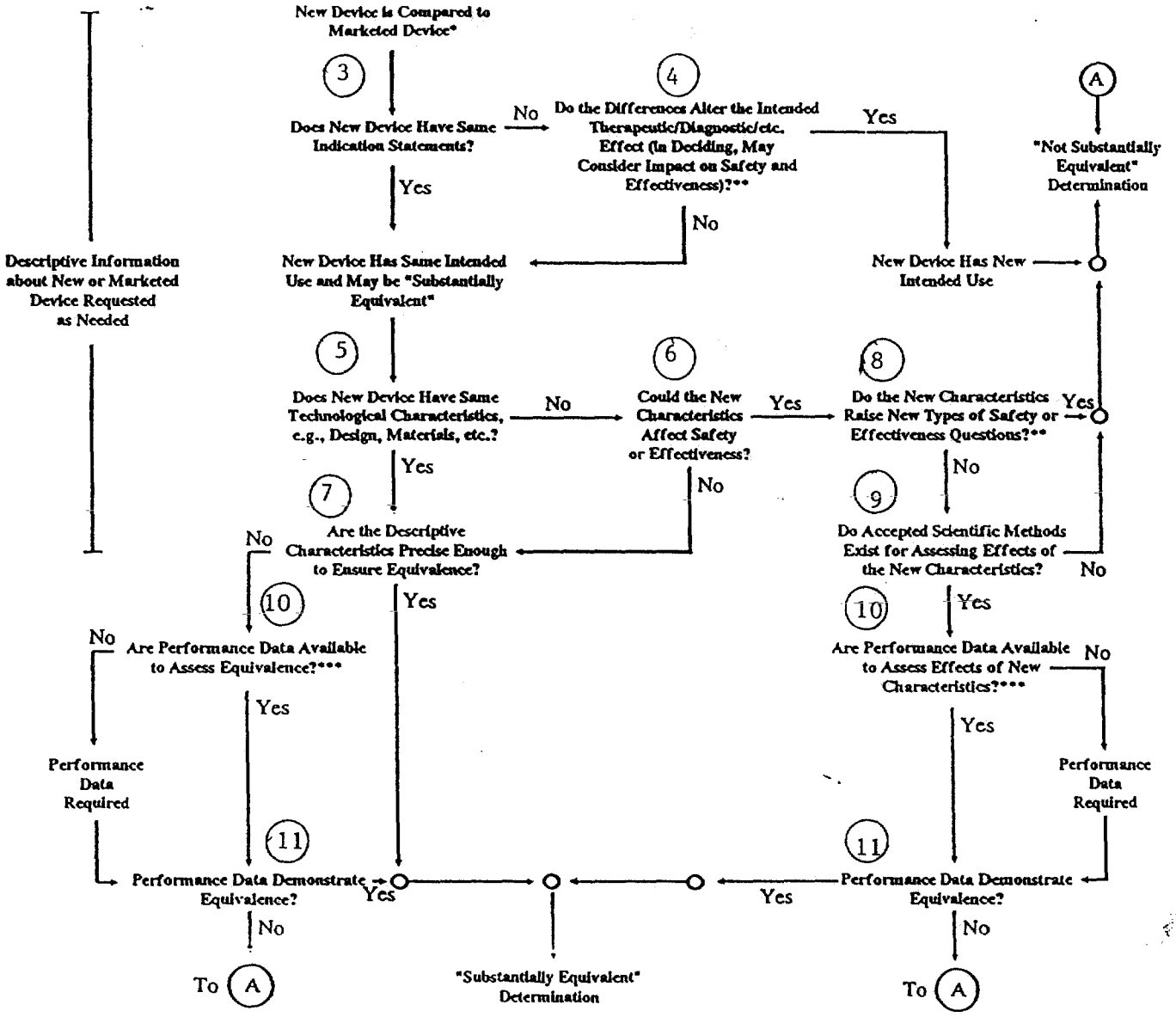
____

REVIEW: [signature] (BRANCH CHIEF) 65JB (BRANCH CODE) 3/15/94 (DATE)

FINAL REVIEW: [signature] (DIVISION DIRECTOR) 3/15/94 (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS Revised: 11/18/91

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

6 J
3/15/94

Department of Health and Human Services **Public Health Service**
Food and Drug Administration

MEMORANDUM

From: R. Weiblinger, Biologist
ODE/DGRD/GSDB

Subject: K940466
Forceps for Electrosurgical Procedures

To: Record

Review of K940466
Original

Submission date: 1/29/94
Received date: 2/2/94
Review date: 3/14/94

Sponsor: Radionics, Inc.
ATTN: Linda Jalbert
P.O. Box 438
22 Terry Avenue
Burlington, MA 01803-2591
617-272-1233

Device: Forceps for Electrosurgical Procedures (bipolar)

Category: *Class II*
Product code: 79 GEI (electro surgical)

Introduction:

The application is for varous sizes of electrosurgical forceps. The subject devices are intended to be used in electro-surgery.

Predicate Devices:

Forceps manufactured by Kirwan Inc. and devices manufactured by Codman, Inc. and Valleylab.

Proposed Indication:

The subject devices are forceps for electrosurgical procedures. The intended use for the devices are the same as that for the predicate device.

Labeling:

The firm has provided a draft copy of the subject device labels. The package label includes intended use. The devices are provided non-sterile with the firm providing recommendations on gas or steam sterilization.

Device Description:

The subject devices are various configurations of forceps for electrosurgical procdures to be supplied non-sterile. The basic method of operation for the devices are similar to that used in previously cleared electrosurgical froceps. The firm has provided diagrams of the subject devices.

Since these devices are patient contacting devices, the firm has provided the materials used in the new device (i.e. (b) (4)) with a comparison of the material to the equivalent device. Material to be used in the devices is titianium, thus biocompatibility of those functional parts that come in contact with patients is deemed proven.

Biocompatibility information on the device material have been provided. The use of the material (i.e. titanium) in prior 510(k) cleared devices has been established and has been discussed with N. Ogden DGRD/GSDB.

The firm has provided information (see comparison chart provided) regarding how the device is similar to and different from the predicate marketed devices. The subject device is comparable to other marketed devices.

Device Description - deficiencies

Since these devices have electrosurgical capabilities the following information is needed:

a. **The forceps must conform with ANSI/AAMI, HF-18, 1993 design standards for electrosurgical devices. Performance evaluation testing information may be provided to FDA.**

b. **a description of the types of electrosurgical generators that are compatible with these devices must be provided.**

The following have been considered:

Is the device life-supporting or life sustaining?	No
Is the device implanted (short-term or long-term)?	No
Does the device design use software?	No
Level of concern for software (if applicable)	NA
Is the device sterile	No
Is the device for single use?	No
Is the device for home use or prescription use?	No
Does the device contain drug or biological products as a component?	No
Is this device a kit?	No

Reviewer's Comments:

The device description characterizes devices which offer a similar system in operational characteristics from the predicate device.

Sterilization:

The devices will be provided non-sterile. The devices are reusable, and the firm has identified the resterilization methods to be used.

Safety and Effectivness Information:

The firm has provided a summary of safety and effectivness.

Conclusion:

The sponsor is claiming substantial equivalence to other marketed devices. The firm has identified and presented evidence of a product presently being marketed in the United States and FDA is aware of other similar products being marketed by other firms.

Recommended Regulatory Action:

The firm was contacted by telephone on 2/14/94 and the above issues were discussed with the firm. The firm indicated thast they would forward the requested infomantion to FDA with hardcopy. This application is recommended to be placed on hold.

Richard Paul Weiblinger

cc: RWeiblinger ODE/DGRD/GSDB
Gen Surg Div File

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February 16, 1994

RADIONICS, INC.
P.O. BOX 438
22 TERRY AVENUE
BURLINGTON, MA 01803
ATTN: LINDA JALBERT

510(k) Number: K940466
Received: 02-FEB-94
Product: TITANIUM BIPOLAR FORCEPS

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.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. Although the traditional timeframes for reviewing 510(k)s has been 90 days, it is now taking longer. These increasing response times have been caused by many factors, including a sharp increase in ODE's workload and increasingly complex device submissions. During 1992, we received about 1,500 more total submissions than we did the preceding year. We are troubled by these increases in response times and are making every effort to regain predictability in the timing of 510(k) reviews. Due to the increase in response times, CDRH has established a 510(k) Status Reporting System through which submitters may receive a status report on their 510(k) submissions(s) as follows:

- Beginning 90 days after ODE receives your 510(k) submission, you may begin requesting status information. Submit requests via fax (301-443-8818) or via mail to:
  510(k) Status Coordinator
  Division of Small Manufacturers Assistance (DSMA) (HFZ-220)
  Center for Devices and Radiological Health, FDA
  5600 Fishers Lane
  Rockville, Maryland 20857
  Because of staff limitations, we cannot accept telephone requests.

- 510(k) status requests should include:
  (1) submitter's name and mailing address;
  (2) requester's name, affiliation with the 510(k) submitter, mailing address, fax number (if applicable), telephone number, and signature; and

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(3) 510(k) information, including product name, 510(k) number, date logged in by ODE (as identified in acknowledgment letter from ODE), and name of contact person identified on firm's 510(k) submission.

Enclosed is a suggested format that you may use to ensure that you include all of the required information.

- Within three working days after DSMA receives a submitter's status request, DSMA will send the submitter a fax or letter that includes:
  (1) the branch to which the 510(k) has been assigned;
  (2) the last action, and date of that action, that CDRH has taken regarding the 510(k), e.g., logging in an amendment, preparing a decision letter; and
  (3) the position of the 510(k) in the reviewer's queue.

We request that 510(k) submitters make status inquiries no more than every four weeks. We do not have the resources to respond more frequently.

The SMDA also requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages 510(k) submitters to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. **Since the law requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.**

Additionally, the new legislation also requires that any person who submits a premarket notification under section 510(k) for a device that asserts that their device is substantially equivalent to any preamendments class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available to him or her about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The

description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

As of March 9, 1993, FDA has implemented the Good Manufacturing Practice(GMP) Pre-Clearance Inspection Program for all class III devices that are being reviewed under the premarket notification program. A letter of substantial equivalence cannot be sent until the finished device manufacturing site(s) and sterilization sites(s) as appropriate, have been identified and FDA has determined that the manufacturer(s) is in compliance with the GMP regulation (21 CFR Part 820).

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the letterhead address. Correspondence sent to other addresses or the Document Mail Center will not be considered part of your official premarket notification submission. Because of expense 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.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

PREMARKET NOTIFICATION (510(k)) STATUS REQUEST

TO: 510(k) Status Coordinator
Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health, FDA
5600 Fishers Lane
Rockville, MD 20857
USA
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

____ fax
____ mail

A. Sponsor Information:

1. Name of 510(k) sponsor: _____

2. Sponsor's mailing address: _____

_____

_____

B. Requester information:

1. Request name: _____

2. Requester affiliation with sponsor: _____

3. Requester mailing address: _____

_____

_____

4. Request fax number (if applicable): _____

5. Requester telephone number: _____

C. 510(k) information:

1. Product name: _____

2. 510(k) number: _____

3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): _____

Name of contact person identified on firm's 510(k) submission: _____

I certify that the above information is accurate and truthful to the best of my knowledge.

(Rev:2) _____ Requester signature

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K940466

RADIONICS, INC.

P.O. BOX 438, 22 TERRY AVE., BURLINGTON, MASSACHUSETTS 01803-2591, U.S.A.
TELEPHONE (617) 272-1233 – FAX: (617) 272-2428

January 29, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Subject: 510(k) for Titanium Bipolar Forceps

To whom it may concern:

This document addresses the Radionics Titanium Bipolar Forceps, Series BFT.

The registration number of our establishment is 1219140.

No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act.

Two copies of the 510(k) are enclosed.

If you have any questions, please call me at (617) 272-1233.

Sincerely yours,

RADIONICS, INC.

(b) (6)

Linda Jalbert
Manager, Regulatory Affairs

Attachment

Table of Contents:

Cortical Surface & Depth Electrode Accessory 510(k)
General Device Summary

Device:	Bipolar Forceps Accessory to electrosurgical coagulation device which is used to remove tissue and control bleeding by use of high frequency electrical current.
Proprietary Trade Name	Titanium Bipolar Forceps
Establishment Registration Number:	1219140
Classification:	Class II
Performance Standard:	No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act.
Intended Use:	These forceps are intended for use with commercially available bipolar coagulator systems for cutting and coagulation of tissue.

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Equivalency Information

Statement of Substantial Equivalence:

Radionics, Inc. believes that the various models of RADIONICS Bipolar Forceps addressed in this premarket notification are substantially equivalent to various Kirwan Bipolar Forceps, Codman Bipolar Forceps and Valleylab Bipolar Forceps. Product literature on the predicate devices is included in Appendix 2.

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Device Description:

Introduction:

Radionics intends to begin marketing various sizes and models of Titanium Bipolar Forceps for use with commercially available bipolar coagulator systems.

Detailed Description

Radionics titanium bipolar forceps are designed in a variety of lengths, styles and tip diameters to accommodate a range of surgical requirements and preferences. Titanium forceps are lighter than stainless steel and are the choice of some physicians especially for long procedures. The styles and sizes covered in this 510(k) are equivalent to Kirwan, Codman and Valley Lab commercially available forceps. Kirwan, Codman and Valley Lab offer various styles in Titanium. Like the Valleylab forceps, the Radionics Titanium forceps are (b) (4) [redacted].

BFT irrigating forceps have a standard luer at the end of the forceps to connect to an irrigating fluid bag. Irrigation is used to reduce heating and sticking of tissue to the forceps. The irrigating tube ends at least 5 mm from the tips of the forceps and does not contact the patient.

CONFIDENTIAL

Radionics is making the BFT forceps from (b) (4) [redacted]. This is the only patient contacting material in the BFT forceps.

Drawings with dimensions of the Radionics Titanium forceps are included in the following pages.

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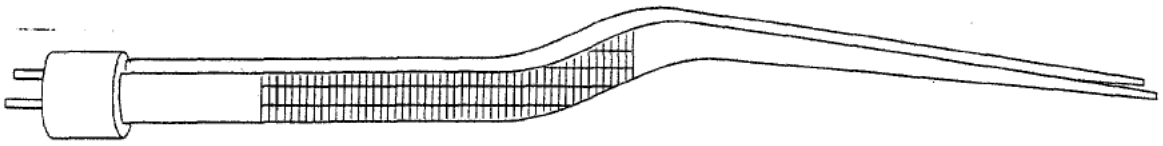
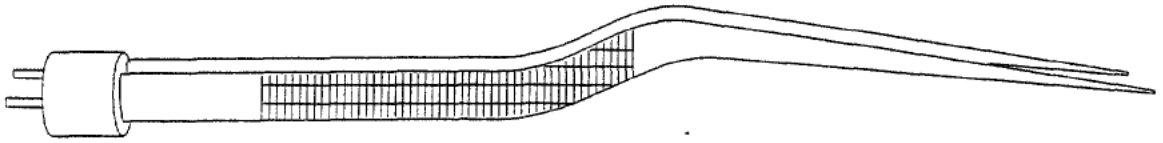
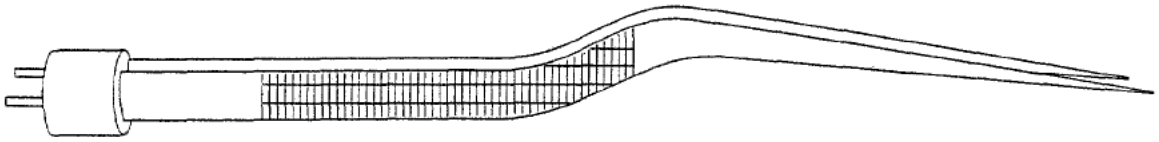


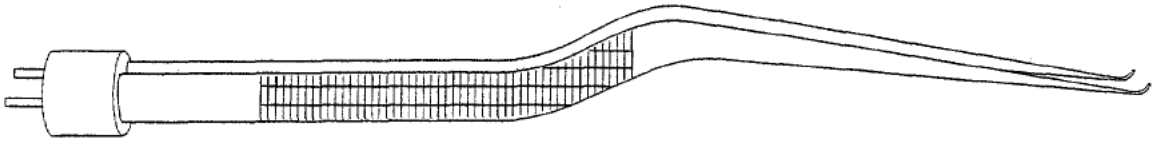
BFT-20 8 3/4" Titanium Bayonet Straight, 1.5mm Tip



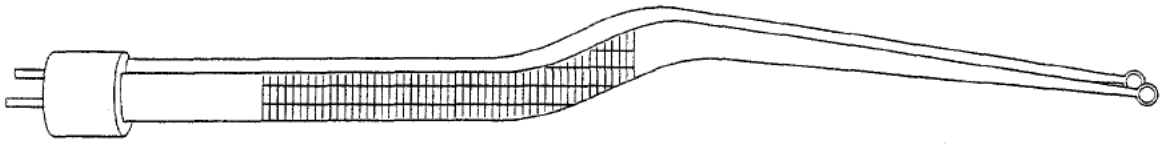
BFT-21 8 3/4" Titanium Bayonet Straight, 1.0mm Tip



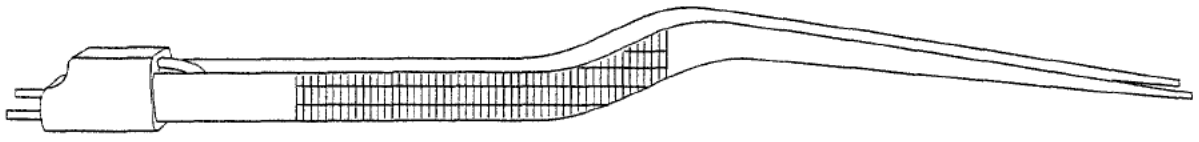
BFT-22 8 3/4" Titanium Bayonet Straight, 0.5mm Tip



BFT-23 8 3/4" Titanium Bayonet Angled-up 22°, 0.5mm Tip



BFT-24 8 3/4" Titanium Bayonet, 5mm Ring Tip



BFT-25 8 3/4" Titanium Irrigating Bayonet Straight, 1.5mm Tip

BFT-26 6" Titanium Straight, 0.5mm Tip

BFT-27 6" Titanium Straight, 0.25mm Tip

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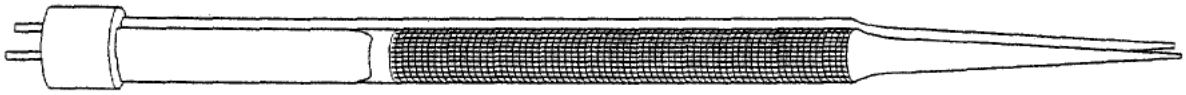
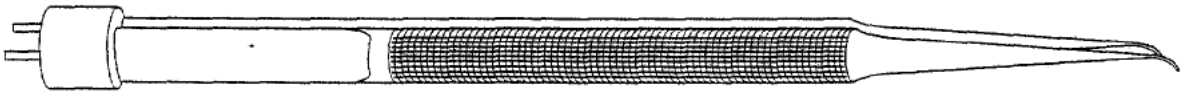
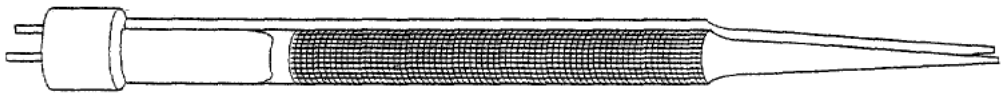


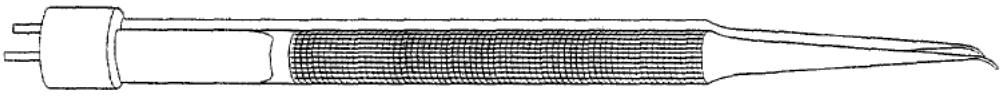
BFT-28 7 1/8" Titanium Round Handle Straight, 0.5mm Tip



BFT-29 7 1/8" Titanium Round Handle Curved, 0.5mm Tip

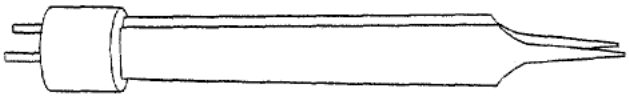


BFT-30 6" Titanium Round Handle Straight, 0.5mm Tip

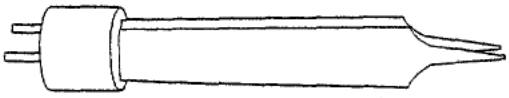


BFT-31 6" Titanium Round Handle Curved, 0.5mm Tip

BFT-32 4 3/4" Titanium Straight, 0.4mm Tip



BFT-33 4 1/4" Titanium Jewelers Straight, 0.4mm Tip



BFT-34 3 1/2" Titanium Jewelers Straight, 0.4mm Tip

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Comparison Matrix:

The following matrices compare RADIONICS Titanium Bipolar Forceps to the Kirwan, Codman and Valleylab forceps.

Component/ Feature	RADIONICS Titanium Bipolar Forceps - Various Models	Kirwan Bipolar Forceps - Various Models	Codman Bipolar Forceps - Various Models	Valleylab Bipolar Forceps - Various Models
Indications for Use:	For use with bipolar coagulator, to cut and coagulate tissue with high frequency electrical current	For use with bipolar coagulator, to cut and coagulate tissue with high frequency electrical current	For use with bipolar coagulator, to cut and coagulate tissue with high frequency electrical current	For use with bipolar coagulator, to cut and coagulate tissue with high frequency electrical current
Material	Titanium	Titanium	Titanium	Titanium

Component/ Feature	RADIONICS Titanium Bipolar Forceps	Kirwan Bipolar Forceps	Codman Bipolar Forceps	Valleylab Bipolar Forceps
Model	BFT-20	15-5101	80-1551	E4071
Style	Bayonet	Bayonet	Bayonet	Bayonet
Length	8 3/4"	8 3/4"	8 3/4"	8 3/4"
Tip Size	1.5 mm	1.5 mm	1.5 mm	1.5 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Ti
Model	BFT-21	15-5103	80-1553	E4073
Style	Bayonet	Bayonet	Bayonet	Bayonet
Length	8 3/4"	8 3/4"	8 3/4"	8 3/4"
Tip Size	1.0 mm	1.0 mm	1.0 mm	1.0 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Ti
Model	BFT-22	15-5102	80-1550	E4072
Style	Bayonet	Bayonet	Bayonet	Bayonet
Length	8 3/4"	8 3/4"	8 3/4"	8 3/4"
Tip Size	0.5 mm	0.5 mm	0.5 mm	0.5 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Ti
Model	BFT-23	15-5104	80-1554	E4074
Style	Bayonet	Bayonet	Bayonet	Bayonet
Length	8 3/4"	8 3/4"	8 3/4"	8 3/4"
Tip Size	0.5 mm	0.5 mm	0.5 mm	0.5 mm
Tip Shape	Angled-up 22°	Angled-up	Angled-up	Angled-up
Material	Ti	Ti	Ti	Ti

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Component/ Feature	RADIONICS Titanium Bipolar Forcep	Kirwan Bipolar Forcep	Codman Bipolar Forcep	Valleylab Bipolar Forcep
Model	BFT-24		80-1230	
Style	Bayonet		Bayonet	
Length	8 3/4"		8 3/4"	
Tip Size	5 mm diameter		5 mm diameter	
Tip Shape	Circular Loop		Circular Loop	
Material	Ti		Ti	
Model	BFT-25		80-1219	
Style	Bayonet, Irrigating		Bayonet, Irrigating	
Length	8 3/4"		8 3/4"	
Tip Size	1.5 mm		1.5 mm	
Tip Shape	Straight		Straight	
Material	Ti		Ti	
Model	BFT-26	15-5112	80-1552	E4052
Style	Straight	Straight	Straight	Straight
Length	6"	6"	6"	6"
Tip Size	0.5 mm	0.5 mm	0.5 mm	0.7 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Stainless Steel
Model	BFT-27	15-5110	80-1554	
Style	Straight	Straight	Straight	
Length	6"	6"	6"	
Tip Size	0.25 mm	0.25 mm	0.25 mm	
Tip Shape	Straight	Straight	Straight	
Material	Ti	Ti	Ti	
Model	BFT-28	15-4103	80-1704	E4056
Style	Straight, Round Handle	Straight, Round Handle	Straight, Round Handle	Straight
Length	7 1/8"	7 1/8"	7"	7"
Tip Size	0.5 mm	0.5 mm	0.5 mm	0.7 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Stainless Steel
Model	BFT-29	15-4104	80-1704	
Style	Straight, Round Handle	Straight, Round Handle	Straight, Round Handle	
Length	7 1/8"	7 1/8"	7"	
Tip Size	0.5 mm	0.5 mm	0.5 mm	
Tip Shape	Curved	Curved	Straight	
Material	Ti	Ti	Ti	
Model	BFT-30	15-4101	80-1704	E4052
Style	Straight, Round Handle	Straight, Round Handle	Straight, Round Handle	Straight
Length	6"	6"	7"	6"
Tip Size	0.5 mm	0.5 mm	0.5 mm	0.7 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Stainless Steel

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Component/ Feature	RADIONICS Titanium Bipolar Forceps	Kirwan Bipolar Forceps	Codman Bipolar Forceps	Valleylab Bipolar Forceps
Model	BFT-31	15-4102	80-1704	
Style	Straight, Round Handle	Straight, Round Handle	Straight, Round Handle	
Length	6"	6"	7"	
Tip Size	0.5 mm	0.5 mm	0.5 mm	
Tip Shape	Curved	Curved	Straight	
Material	Ti	Ti	Ti	
Model	BFT-32	15-3101	80-1220	
Style	Straight	Straight	Straight	
Length	4 3/4"	4 3/4"	6"	
Tip Size	0.4 mm	0.4 mm	0.45 mm	
Tip Shape	Straight	Straight	Straight	
Material	Ti	Ti	Ti	
Model	BFT-33	15-3104	80-1230	E4055
Style	Jewelers	Jewelers	Jewelers	Jewelers
Length	4 1/4"	4 1/4"	4 3/4"	4"
Tip Size	0.4 mm	0.4 mm	0.5 mm	0.4 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	Ti	Stainless Steel
Model	BFT-34	15-2105	80-1206	E4055
Style	Jewelers	Jewelers	IRIS	Jewelers
Length	3 1/2"	3 1/2"	3 5/8"	4"
Tip Size	0.4 mm	0.4 mm	0.6 mm	0.4 mm
Tip Shape	Straight	Straight	Straight	Straight
Material	Ti	Ti	N/A	Stainless Steel

Labeling

Draft Radionics Titanium Bipolar Forceps labeling is included in the following section.

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RADIONICS

Neurosurgical Instruments

Titanium Bipolar Forceps

Description:

The Radionics BFT Titanium Bipolar Forceps are available in a variety of lengths, styles, and tip configurations to accommodate a wide range of surgeon preferences and requirements. These uninsulated forceps are designed for precision and stable tip alignment, comfortable balance and feel and durability. The BFT forceps have the following features:

- Balanced to fit in the web of the surgeon's hand for effortless control
- Standard pin jacks make forceps compatible with most bipolar coagulator systems
- (b) (4)

Catalog No.	Style	Length	Tip Diameter	Tip Configuration
BFT-20	Bayonet	8 3/4"	1.5 mm	Straight
BFT-21	Bayonet	8 3/4"	1.0 mm	Straight
BFT-22	Bayonet	8 3/4"	0.5 mm	Straight
BFT-23	Bayonet	8 3/4"	0.5 mm	Angled-up 22°
BFT-24	Bayonet	8 3/4"	5 mm diameter	Circular Loop
BFT-25	Bayonet, Irrigating	8 3/4"	1.5 mm	Straight
BFT-26	Straight	6"	0.5 mm	Straight
BFT-27	Straight	6"	0.25 mm	Straight
BFT-28	Straight, Round Handle	7 1/8"	0.5 mm	Straight
BFT-29	Straight, Round Handle	7 1/8"	0.5 mm	Curved
BFT-30	Straight, Round Handle	6"	0.5 mm	Straight
BFT-31	Straight, Round Handle	6"	0.5 mm	Curved
BFT-32	Straight	4 3/4"	0.4 mm	Straight
BFT-33	Jewelers	4 1/4"	0.4 mm	Straight
BFT-34	Jewelers	3 1/2"	0.4 mm	Straight

Use

These forceps are intended for use with bipolar coagulator systems to remove tissue and control bleeding by use of high frequency electrical current.

CAUTION: The lowest power setting possible on the coagulator should be used to achieve coaguation. Radionics Titaniumn Bipolar Forceps are uninsulated. It is recommended that insulated forcpes are used when higher power settings are used.

Clean the forceps after each use and sterilize.

Sterilization Procedure:

Sterilization of all the above items shall be done by gas sterilization or steam autoclaving (270° F at 30 psi for 10 min.).

CAUTION:

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

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APPENDIX 1

Summary of Safety and Effectiveness:

I. General Information

Classification:	Class II
Common Name:	Bipolar Forceps
Device Trade Name:	Titanium Bipolar Forceps BFT
Intended Uses:	Accessories to electrosurgical coagulation device, used to remove tissue and control bleeding by use of high frequency electrical current.
Predicate Device:	Various styles and models of: Kirwan Bipolar Forceps, Codman Bipolar Forceps and Valleylab Bipolar Forceps
Establishment Name and Address:	Radionics, Inc. P.O. Box 438, 22 Terry Ave. Burlington, MA 01803
Contact Name and Phone:	Linda Jalbert, (617) 272-1233
Establishment registration number:	1219140
Performance Standard:	None established under Section 514 of the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information supporting the Substantial Equivalence Determination.

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

General Safety and Effectiveness Concerns

RADIONICS BFT Titanium Bipolar Forceps labeling contains instructions for the proper use of these accessories. It includes a description of the products, directions for use, and applicable safety information. These instructions ensure safe and effective use of the devices when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The Titanium Bipolar Forceps accessories addressed in this premarket notification have the same intended use and technological characteristics as the commercially available Kirwan, Codman and Valleylab Bipolar Forceps. Like the Kirwan, Codman and Valleylab Bipolar Forceps, RADIONICS Bipolar Forceps are designed to be used with commercially available electrosurgical coagulation devices, to remove tissue and control bleeding by use of high frequency electrical current. Kirwan, Codman and Valleylab market various models of Titanium bipolar forceps. The RADIONICS Bipolar Forceps are offered in a variety of styles, lengths and tip configurations; the styles, lengths, and tip configurations are equivalent to forceps marketed by Kirwan, Codman and Valleylab.

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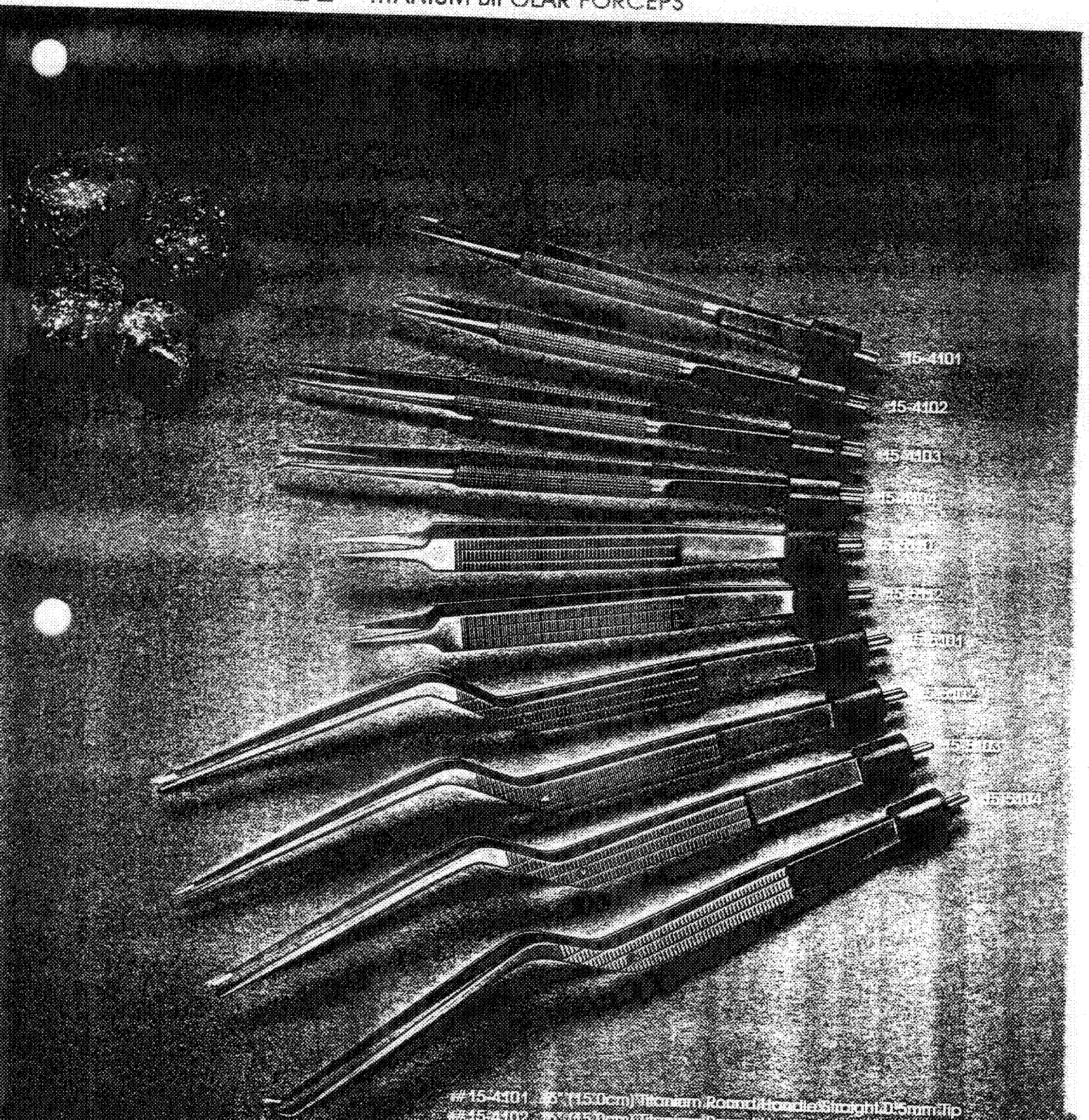
APPENDIX 2

KIRWAN

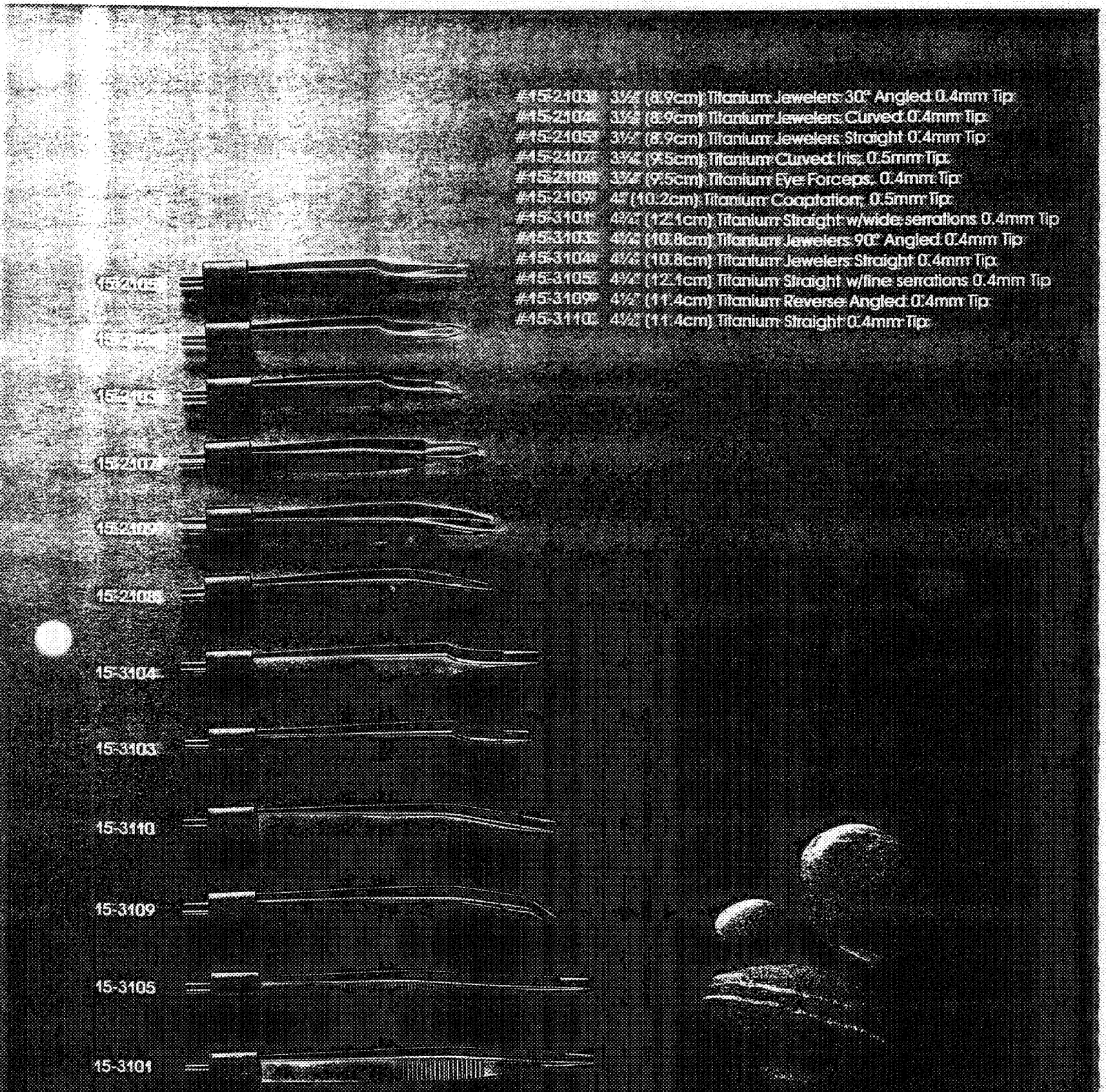
TITANIUM BIPOLAR FORCEPS



#15-4101 6" (15.0cm) Titanium Round Handle Straight 0.5mm Tip
#15-4102 6" (15.0cm) Titanium Round Handle Curved 0.5mm Tip
#15-4103 7¼" (18.4cm) Titanium Round Handle Straight 0.5mm Tip
#15-4104 7¼" (18.4cm) Titanium Round Handle Curved 0.5mm Tip
#15-5101 8¾" (22.2cm) Titanium Bayonet Straight Regular 1.5mm Tip
#15-5102 8¾" (22.2cm) Titanium Bayonet Straight Fine 0.5mm Tip
#15-5103 8¾" (22.2cm) Titanium Bayonet Straight Medium 1.0mm Tip
#15-5104 8¾" (22.2cm) Titanium Bayonet Angled-up Fine 0.5mm Tip
#15-5110 6" (15.0cm) Titanium Straight 0.25mm Tip
#15-5112 6" (15.0cm) Titanium Straight 0.5mm Tip

TITANIUM BIPOLAR FORCEPS

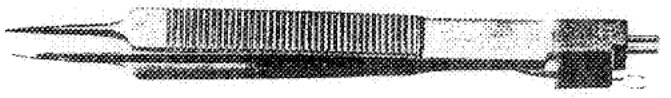
#15-2103: 3½" (8.9cm) Titanium Jewelers 30° Angled 0.4mm Tip
#15-2104: 3½" (8.9cm) Titanium Jewelers Curved 0.4mm Tip
#15-2105: 3½" (8.9cm) Titanium Jewelers Straight 0.4mm Tip
#15-2107: 3¾" (9.5cm) Titanium Curved Iris, 0.5mm Tip
#15-2108: 3¾" (9.5cm) Titanium Eye Forceps, 0.4mm Tip
#15-2109: 4" (10.2cm) Titanium Coaptation, 0.5mm Tip
#15-3101: 4¾" (12.1cm) Titanium Straight w/wide serrations 0.4mm Tip
#15-3103: 4¼" (10.8cm) Titanium Jewelers 90° Angled 0.4mm Tip
#15-3104: 4¼" (10.8cm) Titanium Jewelers Straight 0.4mm Tip
#15-3105: 4¾" (12.1cm) Titanium Straight w/fine serrations 0.4mm Tip
#15-3109: 4½" (11.4cm) Titanium Reverse Angled 0.4mm Tip
#15-3110: 4½" (11.4cm) Titanium Straight 0.4mm Tip



FORCEPS, BIPOLAR IRRIGATING

MALIS Bipolar Irrigating Forceps, used in conjunction with the Malis Irrigation Module (80-1164)

80-1125



80-1216

80-1222

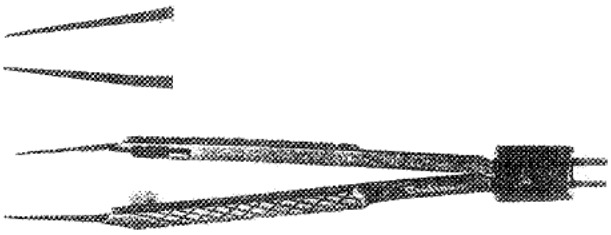
80-1230

80-1231

80-1232

	Style	Length	Alloy	Tip Configuration	Tip Size
80-1122	Bayonet	8½" (21.3cm)	Insulated Stainless	Straight	0.70mm
80-1123	Straight	5" (13.9cm)	Insulated Stainless	Straight	0.75mm
80-1124	Bayonet	7¾" (19.7cm)	Insulated Stainless	Straight	1.0mm
80-1125	Bayonet	8½" (21.3cm)	Titanium	Straight	0.50mm
80-1129	Bayonet	7¾" (19.7cm)	Insulated Stainless	Straight	0.25mm
80-1215	Straight	6" (15.2cm)	Titanium	Straight	0.25mm
80-1216	Straight	5" (13.9cm)	Insulated Stainless	Straight	0.25mm
80-1217	Straight	7" (18cm)	Insulated Stainless	Straight	0.25mm
80-1218	Bayonet	7¾" (19.7cm)	Insulated Stainless	Straight	0.25mm
80-1219	Bayonet	8¾" (22.4cm)	Titanium	Straight	1.5mm
80-1220	Straight	6" (15cm)	Titanium	Straight	0.45mm
80-1221	Bayonet	8¾" (22.4cm)	Titanium	Straight	1.0mm
80-1222	Bayonet	8¾" (22.4cm)	Titanium	Angle Up	0.50mm
80-1223	Bayonet	8¾" (22.4cm)	Titanium	Angle Down	0.50mm
80-1224	Bayonet	8¾" (22.4cm)	Titanium	90° Blunt Curve Up	0.75mm
80-1225	Bayonet	8¾" (22.4cm)	Titanium	Straight	0.25mm
80-1226	Bayonet	8¾" (22.4cm)	Titanium	90° Blunt Curve Down	0.75mm
80-1230	Bayonet	8¾" (22.4cm)	Insulated Titanium	Circular Loop	5mm
80-1231	Bayonet	8¾" (22.4cm)	Insulated Titanium	Circular Loop	7mm
80-1232	Bayonet	8¾" (22.4cm)	Insulated Titanium	Circular Loop	10mm

COAGULATORS
FORCEPS, BIPOLAR



E-SERIES * Bipolar Forceps, straight, TITANIUM.
Unique tip alignment system.
Closing Pressure 75 gms. (approximate)

	Length	6"	(150mm)
80-6011	Fine	Tip width	.25mm
80-6012	Regular	Tip width	1mm

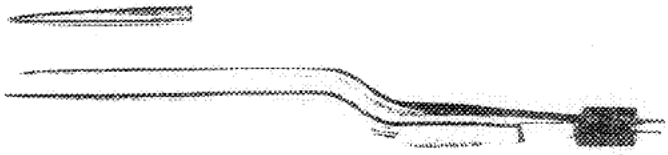
30-1286 GERALD Bipolar Forceps, straight.

Tip width		.87mm
Length	7¼"	(184mm)

GREENWOOD Bipolar and Suction Forceps, bayonet.

Working distance	3¼"	(83mm)
Tip width		1.75mm
Length	7"	(178mm)

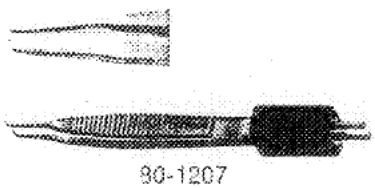
30-1525 Forceps
30-1526 Forceps with insulation



30-1235 HARDY Bipolar Forceps, bayonet.

Working distance	4¾"	(121mm)
Tip width		.7mm
Length	8¼"	(210mm)

80-1206



80-1207

IRIS Bipolar Forceps, straight.

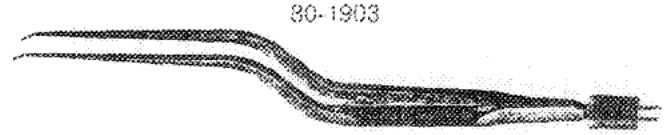
Tip width		.6mm
Length	3⅝"	(92mm)

80-1206 Straight
80-1207 Curved

Codmar

COAGULATORS
FORCEPS, BIPOLAR

80-1903



80-1904

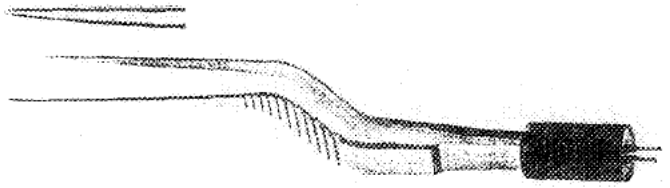
SPETZLER Neuro-Vascular Bipolar Forceps
Titanium, bayonet

	Length	9½"	(24
	Working distance	4"	(100
			Tip
80-1903	Bipolar Forceps,	straight tip	.7mm
80-1904	Bipolar Forceps,	30° angled tip	.7mm

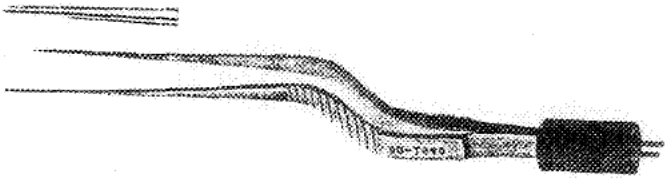
NOTE: See back of NEUROSURGICAL Section for list of all Malis, Rhoton and Spetzler instruments.

80-1204	STANDARD Bipolar Forceps, straight.		
	Tip width		.5mm
	Length	3⅝"	(92mm)

80-1632



80-1635



80-1640

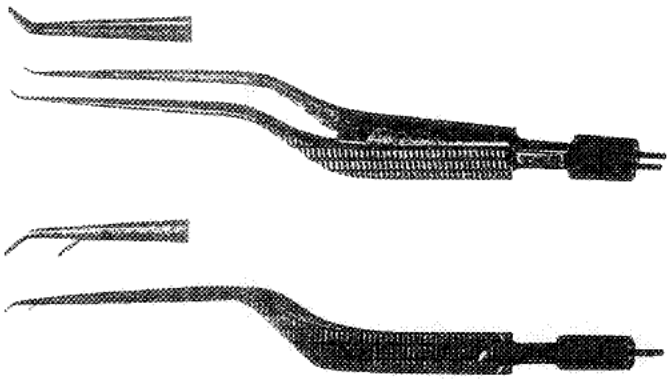
YASARGIL Bipolar Forceps, bayonet.

	Working distance	2½"	(64mm)
	Length	6¾"	(171mm)
80-1630	Fine	Tip width	.5mm
80-1631	Medium	Tip width	.7mm
80-1632	Regular	Tip width	1mm
	Working distance	3"	(76mm)
	Length	7¼"	(184mm)
80-1634	Fine	Tip width	.5mm
80-1635	Medium	Tip width	.7mm
80-1636	Regular	Tip width	1mm
80-1637	Large	Tip width	1.3mm
	Working distance	4"	(102mm)
	Length	8¼"	(210mm)
80-1638	Fine	Tip width	.5mm
80-1639	Medium	Tip width	.7mm
80-1640	Regular	Tip width	1mm
80-1641	Large	Tip width	1.3mm

COAGULATORS
FORCEPS, BIPOLAR

1206 ADSON Bipolar Forceps, straight.
Tip width 1mm
Length 4¾" (120mm)

APPELBAUM Bipolar Forceps, bayonet
TITANIUM.
Working distance 3½" (89mm)
Tip width .5mm
Length 7¼" (184mm)
1675 45° Angled up
1677 45° Angled down

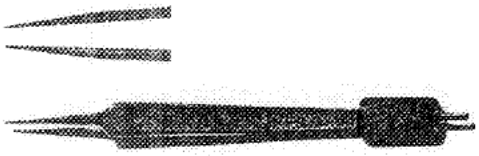


COAPTATION Bipolar Forceps, straight.
Small
Tip width .25mm
Length 4" (102mm)
1212 Large
Tip width .4mm
Length 4½" (114mm)

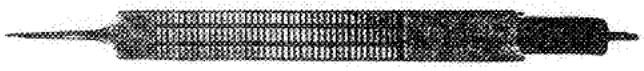
CUSHING Bipolar Forceps, straight.
Tip width 1.5mm
Length 7" (178mm)
Forceps only
Forceps only with insulation

FORCEPS, BIPOLAR

80-1716	JEWELERS #5 Bipolar Forceps, straight.		
	Tip width		.5mm
	Length	4¾"	(120mm)

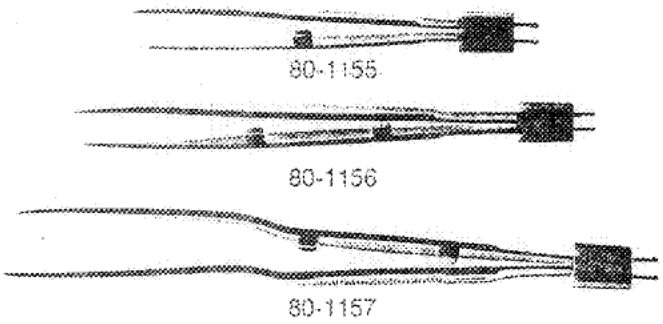


	MALIS Bipolar Forceps, straight, TITANIUM.		
	Length	6"	(152mm)
80-1552	Fine	Tip width	.5mm
80-1557	Extra fine	Tip width	.25mm



MALIS * Bipolar Coagulation and Cutting Forceps
Specifically, designed for use with the MALIS * CMC-II (80-1140, 80-1141).
Forceps are insulated stainless steel.

80-1155	Straight		
	Tip width	.2mm	
	Length	5½"	(140mm)
80-1156	Straight		
	Tip width	.2mm	
	Length	6¾"	(172mm)
80-1157	Bayonet		
	Tip width	.2mm	
	Length	7¾"	(197mm)

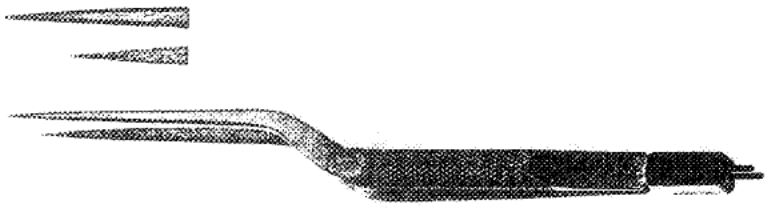


See back of NEUROSURGICAL Section for list of all Malis, Rhoton and Spetzler instruments.

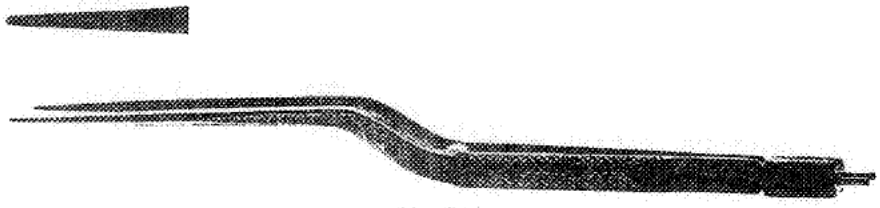
COAGULATORS
FORCEPS, BIPOLAR

RHOTON Bipolar Forceps, straight, TITANIUM.

	Length	7"	(178mm)
80-1704	Fine	Tip width	.5mm
80-1705	Regular	Tip width	1mm



80-1706



80-1713

80-1715

RHOTON Bipolar Forceps, bayonet, TITANIUM

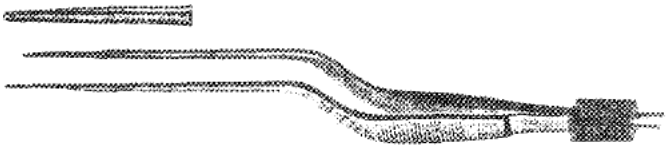
	Working distance	3½"	(89mm)
	Length	8½"	(216mm)
80-1706	Fine	Tip width	.5mm
80-1708	Regular	Tip width	1mm
	Working distance	4"	(102mm)
	Length	9½"	(240mm)
80-1711	Fine	Tip width	.5mm
80-1713	Regular	Tip width	1mm
	Working distance	4¾"	(120mm)
	Length	10¼"	(260mm)
80-1715	Fine	Tip width	.7mm

RHOTON Bipolar Forceps, bayonet, TITANIUM.

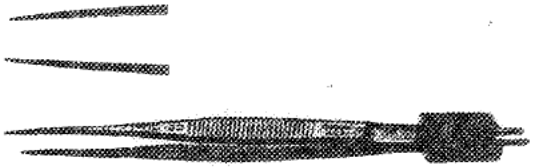
	Working distance	3¾"	(95mm)
	Length	9½"	(240mm)
80-1740	Fine	Tip width	.5mm
80-1741	Medium	Tip width	.7mm
80-1742	Regular	Tip width	1.0mm
80-1743	Large	Tip width	1.5mm

See back of NEUROSURGICAL Section for list of all [illegible] and Spetzler instruments.

COAGULATORS
FORCEPS, BIPOLAR

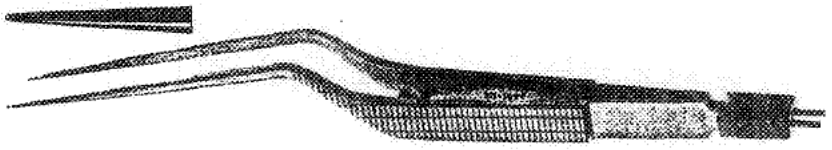


30-1282	MALIS-JENSEN Bipolar Forceps, bayonet.		
	Working distance	4″	(101mm)
	Tip width		.25mm
	Length	7¾″	(197mm)



30-1270	MALIS Bipolar Forceps, straight.		
	Tip width		.75mm
	Length	5½″	(140mm)

	MALIS Bipolar Forceps, bayonet.		
	Working distance	3¼″	(83mm)
	Tip width		1.5mm
	Length	7″	(178mm)
30-1527	Forceps only		
30-1528	Forceps with insulation		



80-1553

80-1554

	MALIS Bipolar Forceps, bayonet, TITANIUM.		
	Working distance	3¾″	(95mm)
	Length	8¾″	(222mm)
			Tip Width
80-1550	Straight, fine tip		.5mm
80-1551	Straight, regular tip		1.5mm
80-1553	Straight, medium tip		1mm
80-1554	Angled up, fine tip		.5mm
80-1555	Angled down, fine tip		.5mm
80-1556	Curved up, blunt tip		.75mm
80-1558	Straight, extra fine tip		.25mm

NOTE: See back of NEUROSURGICAL Section for list of all Malis, Rhoton and Spetzler instruments.

Codman

Valleylab Handswitching and Footswitching Bipolar Forceps.

The profession's choice for quality and precision.

Valleylab, the world leader in electrosurgery, provides a full range of bipolar and micro-bipolar forceps to complement the surgeon's technique in procedures demanding precise bipolar desiccation.

Precision crafted of the highest grade stainless steel and titanium, these quality surgical instruments are designed to provide superior control, safety, and surgical efficacy at minimum output power settings.

The selection includes handswitch and footswitch activated forceps in bayonet, jewelers, iris, and coaptation models. Scoville-Greenwood, Cushing, Gerald, and Hardy styles offer a variety of lengths, tip configurations, and tip diameters to accommodate most surgical requirements.

Handswitching bipolar forceps

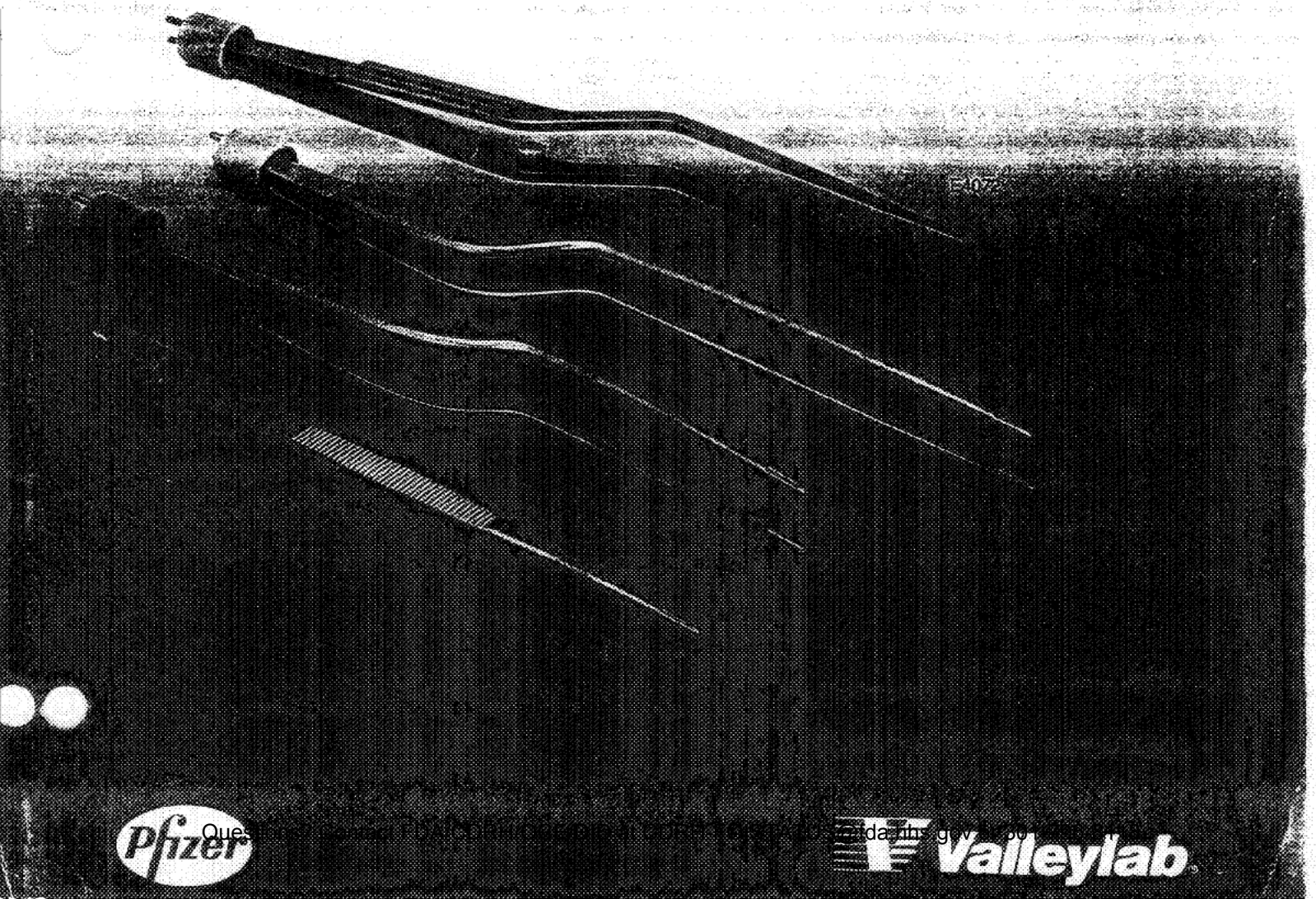
Eliminate searching for the footswitch – especially important during critical procedures. The unique leaf spring hinge delivers consistent pressure over a wide range of tissue thicknesses and improves tactile sensitivity. The superior performance provided by Valleylab handswitching bipolar forceps in combination with Valleylab Force-Series generators minimizes sparking, charring and blanching of adjacent tissue.

Footswitching titanium bipolar forceps

Are the preferred light weight forceps, especially for long, fatiguing procedures. Over 40% lighter than stainless steel, these titanium forceps are anodized for superior corrosion resistance and reduced glare. A combination of raised grid pattern, long handles that rest comfortably in the web of the hand, and an angled bayonet for a straight line between fingers and tips work together to ensure effortless control.

Footswitching stainless steel bipolar forceps

Provide the degree of precision and safety vital to bipolar electrosurgery. Available in a wide variety of styles, lengths, and tip diameters, Valleylab footswitching stainless steel bipolar forceps provide high performance at minimum generator output settings.

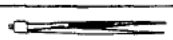
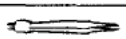


Pfizer

Valleylab

Bipolar Coagulation Forceps:

Technical Specifications

Catalog No.			Description	Length	Tip
Non-Insulated	Insulated				
E4051	E4051CT		Scoville-Greenwood bipolar bayonet forceps	7-3/4 in. (19.7 cm)	1.5 mm
E4052	E4052CT		Cushing bipolar forceps	6 in. (15.2 cm)	0.7 mm
E4053	E4053CT		Cushing bipolar forceps	7 in. (17.8 cm)	1.5 mm
E4054	E4054CT		Cushing bipolar forceps	7-1/2 in. (19.1 cm)	2.0 mm
E4055	E4055CT		Jewelers bipolar forceps, straight tip	4 in. (10.2 cm)	0.4 mm
E4056	E4056CT		Gerald microbipolar forceps	7 in. (17.8 cm)	0.7 mm
E4057	E4057CT		Gerald microbipolar forceps	7-1/2 in. (19.1 cm)	0.7 mm
E4058	E4058CT		Cushing microbipolar forceps	7-1/2 in. (19.1 cm)	0.7 mm
E4059	E4059CT		Hardy type microbipolar bayonet forceps with stops	8-1/4 in. (21.0 cm)	0.5 mm
E4060	E4060CT		Semkin microbipolar forceps with stops	5-1/4 in. (13.3 cm)	0.5 mm
E4061	E4061CT		Straignt iris forceps	3-1/2 in. (8.9 cm)	0.5 mm
E4062	E4062CT		Curved iris forceps	3-1/2 in. (8.9 cm)	0.4 mm
E4063	E4063CT		Coaptation type forceps	4-1/2 in. (11.4 cm)	0.5 mm
E4064	E4064CT		Jewelers bipolar forceps, curved tip	4 in. (10.2 cm)	0.4 mm
E4071	E4071CT		Titanium bayonet forceps, straight regular tip	8-3/4 in. (22.5 cm)	1.5 mm
E4072	E4072CT		Titanium bayonet forceps, straight fine tip	8-3/4 in. (22.5 cm)	0.5 mm
E4073	E4073CT		Titanium bayonet forceps, straight medium tip	8-3/4 in. (22.5 cm)	1.0 mm
E4074	E4074CT		Titanium bayonet forceps, angled up, fine tip	8-3/4 in. (22.5 cm)	0.5 mm
E4080			Scoville-Greenwood bipolar handswitching bayonet forceps	7-3/4 in. (19.7 cm)	1.5 mm
E4081			Semkin microbipolar handswitching forceps	5-1/4 in. (13.3 cm)	0.5 mm
E4084			Gerald microbipolar handswitching forceps	7 in. (17.8 cm)	0.7 mm
E4085			Gerald microbipolar handswitching forceps	7-1/2 in. (19.1 cm)	0.7 mm

Gas sterilization is recommended, as steam autoclaving will reduce the life of the product. Forceps may, however, be steam autoclaved (not to exceed 275°F, 135°C).

Order Information

Catalog No.	Description	Order Quantity
E4051 – E4064 E4051CT – E4064CT	Reusable, noninsulated and insulated stainless steel, footswitching, bipolar coagulation forceps	1 each
E4071 – E4074 E4071CT – E4074CT	Reusable, noninsulated and insulated titanium, footswitching, bipolar coagulation forceps	1 each
E4080 – E4085	Reusable noninsulated stainless steel, handswitching, bipolar coagulation forceps	1 each
E0019	Reusable 12 ft. (3.7 m) bipolar coagulation forceps cord	1 each
E0018	Reusable 12 ft. (3.7 m) silicone, handswitching bipolar coagulation forceps cord	1 each
E0509	Sterile, disposable 12 ft. (3.7 m) bipolar coagulation forceps cord	50/case

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Specifications subject to change without notice.

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