

*Alert ✓
Computer*

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-93-1621

4/16/93

FROM: ACUFEX MICROSURGICAL, INC. ATTN: FREDERICK TOBIA 130 FORBES BLVD. MANSFIELD, MA 02048 SHORT NAME: ACUFMICR	LETTER DATE 04/01/93	LOGIN DATE 04/02/93	DUE DATE 07/01/93
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K931521
		PHONE NO: 508-339-9700 ESTABLISHMENT NO: 1219602	
TO: ODE/DMC	CONT. CONF.: ? STATUS : R REV PANEL : <i>SU OR</i> PAN/PROD CODE(S): <i>SU OR</i> / /		
SUBJECT: ACUFEX PRO-PAC AND ISO-PAC			
DECISION: DECISION DATE: / /	ROST INFO DATE: / / DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: / / DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	

Misroute to ORDB 4/29/93

SU → DMC → OR 5-3-94

Statement ORDB HRX

DMC 1-21-94 SE

JAN 21 1994



JAN 21 1994

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Mr. Frederick Tobia
Registration Manager
Acufex Microsurgical, Inc.
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K931621
Acufex Pro-Pac and Iso-Pac
Regulatory Class: II
Dated: April 1, 1993
Received: April 2, 1993

Dear Mr. Tobia:

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

Page 2 - Mr. Frederick Tobia

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,



for

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



Memorandum

Date

From

REVIEWER(S) - NAME(S)

D. E. Marlowe

Subject

510(k) NOTIFICATION

K931021

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:

87 JL HRX

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

REVIEW:

Daniel S. Marlowe
(BRANCH CHIEF)

02DB
BRANCH CODE

1/19/94
(DATE)

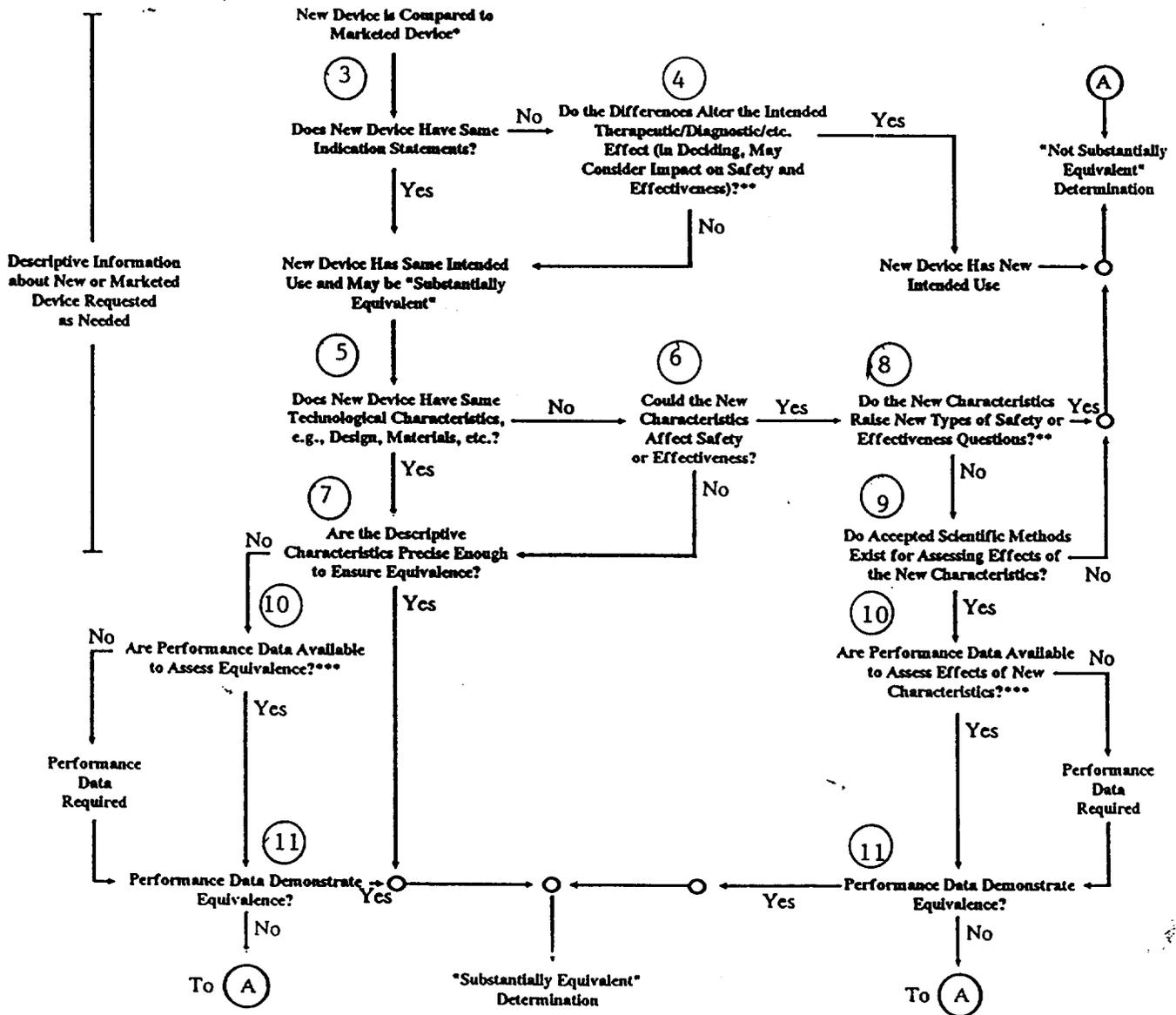
FINAL REVIEW:

[Signature]
(DIVISION DIRECTOR)

1/18/94

(DATE)

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.

10 January 1994

Mechanical Engineer
Division of Mechanics and Materials Science HFZ-150

K931621

File

INTENDED USE: This 510(k) describes two "kits" intended to aid the surgeon in the ligament replacement.

DEVICE DESCRIPTION: The devices are kits containing several components packaged and sterilized together as noted below:

Pro-Pac Kit

- Drill tip guide wire
- Passing pin
- Cannulated Bone Tunnel Plug
- Clear-Trac Cannula
- Cannu-Flex Guide wire

Iso-Pac Kit

- Drill tip guide wire
- Passing pin
- Cannulated Bone Tunnel Plug
- Clear-Trac Cannula
- Cannu-Flex Guide wire
- Isotac pilot wire
- Isotac
- Suture retriever

All components in each kit will be placed in a plastic tray and sealed with a Tyvek cover before gamma radiation sterilization at a dose of 2.5-4.0 MRads.

Several of these components are Class I (exempt). Acufex Microsurgical has provided the 510(k) numbers for those kit components subject to Notification. In addition, the firm has provided the required SMDA statement of availability of safety and effectiveness data.

There are no new materials questions or areas of intended use from the individual devices which make up the kit.

RECOMMENDATION: I recommend that this kit be found substantially

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equivalent to currently marketed devices.

Mr. Frederick Tobia
Registration Manager
Acufex Microsurgical, Inc.
130 Forbes Blvd
Mansfield Massachusetts 02048

Re: K931621
Trade Name: Pro-Pac and Iso-Pac
Regulatory Class: II
Dated: April 1, 1993
Received: April 11, 1993

Dear Mr. Tobia:

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 annual 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 anyway

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-300) 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. Benninger, M.D.
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRD
D.O.

K 931621 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: D. F. HARLOWE DIVISION/BRANCH: OSJ/DMAS

TRADE NAME: Pac-Pac/ISO-Pac COMMON NAME: MANUAL SURGICAL INSTRUMENTS

PRODUCT TO WHICH COMPARED: _____
(510(k) NUMBER IF KNOWN)

YES | (NO)

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

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: _____

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: _____

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

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

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

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

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

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

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

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

APRIL 16, 1993

ACUFEX MICROSURGICAL, INC.
ATTN: FREDERICK TOBIA
130 FORBES BLVD.
MANSFIELD, MA 02048

510(k) Number: K931621
Received: 04-02-93
Product: ACUFEX PRO-PAC AND
ISO-PAC

We have 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. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 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.

In addition, the SMDA 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 manufacturers 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 any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, 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.

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) 227-8006.

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 above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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) 427-1190.

Sincerely yours,

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

ACUFEX MICROSURGICAL, INC.

K 931621

April 1, 1993

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

FDA/CDRH/OCE/DHC

2 APR 93 11 01

RECEIVED

RE: 510(k) Premarket Notification for the Acufex Pro-Pac and Iso-Pac

Dear Sir/Madam:

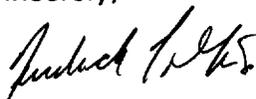
Enclosed are two copies of a 510(k) Premarket Notification, submitted in accordance with 21 CFR 807, Subpart E, for the Acufex Pro-Pac and Iso-Pac, a surgical kit provided sterile containing accessories and instruments for surgical procedures. The intent of this Premarket notification is to combine various currently marketed Acufex components as a kit, sold sterile, for the convenience of the orthopedic surgeon.

We consider our intent to market this device as confidential commercial information and request it be considered as such by the Food and Drug Administration. We have not disclosed our intent to market this device to anyone except consultants and/or employees of our company and have taken precautions to protect this confidentiality.

In accordance with the Safe Medical Devices Act of 1990, any information included in this submission, regarding safety and effectiveness will be made available upon request.

If there are any questions regarding the information included in this Premarket Notification or if any additional information is required, please contact me at (508) 339-9700, ext. 2146.

Sincerely,



Frederick Tobia
Registration Manager

Enclosure(s)

130 FORBES BOULEVARD
MANSFIELD, MASSACHUSETTS 02048
508/339-9700
800/45-ACUFEX (800/452-2833)
FAX 508/339-8853
TELEX 924474

CROWN HOUSE
HORNBEAM SQUARE NORTH
HARROGATE HG 2 8PB ENGLAND
TEL: 0423 879 379
FAX 0423 873 202

**510(k) Premarket Notification
Acufex Microsurgical, Inc.**

510(K) Premarket Notification

**Acufex Microsurgical, Inc.
Pro-Pac and Iso-Pac Surgical Accessory Kits**

Table of Contents

Section

- 1. Company Name and Address**
- 2. Device Name**
- 3. Establishment Registration**
- 4. Classification**
- 5. Performance Standards**
- 6. Labeling**
- 7. Device Description**
- 8. Substantial Equivalence**
- 9. 510K Statement -Availability of Safety and Effectiveness Information**

SECS. 1-5

1. Company Name and Address

Acufex Microsurgical
 130 Forbes Boulevard
 Mansfield, MA 02048

2. Device Name

The devices covered in this premarket notification are a collection of currently marketed Acufex products, compiled in a set of two sterile kits. The intent of this premarket notification is to market these currently marketed accessories as a sterile kit for the convenience of the surgeon.

Proprietary Name(s):

A. Acufex Pro-Pac Kit containing

<u>Instrument</u>	<u>Quantity</u>
Acufex Drill Tip Guide Wire	1
Acufex Passing Pin	1
Acufex Cannulated Bone Tunnel Plug	1
Acufex Clear-Trac Cannula	1
Acufex Cannu-Flex Guide Wire	1

B. Acufex Iso-Pac Kit containing

<u>Instrument</u>	<u>Quantity</u>
Acufex Drill Tip Guide Wire	1
Acufex Passing Pin	1
Acufex Cannulated Bone Tunnel Plug	1
Acufex Clear-Trac Cannula	1
Acufex Cannu-Flex Guide Wire	1
Acufex Isotac Pilot Wire	1
Acufex Isotac	1
Acufex Suture Retriever	1

Common and Classification Names:

Common Name(s)	Classification Name(s)	Classification
Wire, Surgical <ul style="list-style-type: none"> • Drill Tip Guide Wire • Cannu-Flex™ Guide Wire 	Orthopedic manual surgical instruments (87 LRN)	Class I Exempt
Passer, Wire, Orthopedic <ul style="list-style-type: none"> • Passing Pin 	Orthopedic manual surgical instruments (87 HXI)	Class I Exempt
Cannula <ul style="list-style-type: none"> • Cannulated Bone Tunnel Plug • Clear-Trac™ Cannula 	Arthroscope accessories (87 HRX)	Class II
Positioning tool, template <ul style="list-style-type: none"> • Isotac® Pilot Wire • Isotac® 	Orthopedic template for clinical use (87 HWS)	Class I Exempt
Suture Snare, Surgical <ul style="list-style-type: none"> • Suture Retriever 	Manual surgical instrument for general use (79 GAE)	Class I Exempt

3. Establishment Registration

The establishment registration number for Acufex Microsurgical, Inc. is 1219602.

4. Classification

The General and Plastic Surgery Device Panel has classified the following parts of this set as follows:

Surgical Snare, a Manual surgical instrument for general use, is classified as a Class I device (21 CFR 878.4800)

The Orthopedic Device Panel has classified the following parts of this set as follows:

Surgical Wire and Passer Pins are Orthopedic manual surgical instruments classified as Class I devices. (21 CFR 888.4540)

Positioning Tool, an Orthopedic template for clinical use, is classified as a Class I device (21 CFR 888.4800)

Cannula, a Arthroscope accessories, is classified as a Class II device. (21 CFR 888.1100)

5. Performance Standards

No performance standards applicable to this device have been adopted under Section 514 of the Act.

SEC. 6

6. Labeling

The Acufex Iso-Pac and Pro-Pac are sold sterile, for single use only. Draft package labels for the Acufex Iso-Pac and the Acufex Pro-Pac follows. The product insert for the Iso-Pac also follows.

Promotional literature for these products have not been prepared.

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Acufex Pro-Pac Labeling

Tyvek Lid Acufex Pro-Pac

ACUFEX

**PRO - PAC
CRUCIATE ACCESSORY KIT
STERILE**

**CONTENTS ARE STERILE UNTIL
PACKAGE IS DAMAGED OR BROKEN**

NOTE: FEDERAL (USA) LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN
SINGLE USE ONLY. DO NOT RESTERILIZE.

CONTENTS:
CANNULATED BONE TUNNEL PLUG CANNU-FLEX GUIDE WIRE SPADE TIP PASSING PIN
DRILL TIP GUIDE WIRE CLEAR-TRAC CANNULA

ACUFEX MICROSURGICAL, INC.
MANSFIELD, MA 02045 USA

Product Identification Label Acufex Pro-Pac

ACUFEX

CAT. NO. XXX 1 KIT

**PRO - PAC
CRUCIATE ACCESSORY KIT**

STERILIZED BY GAMMA IRRADIATION

LOT NO. XXXXXX 401XXX

Box Label Acufex Pro-Pac

STERILE

**CONTENTS ARE STERILE
UNTIL PACKAGE IS DAMAGED OR BROKEN**

NOTE: FEDERAL (USA) LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN
SINGLE USE ONLY. DO NOT RESTERILIZE.

ACUFEX MICROSURGICAL, INC.
MANSFIELD, MA 02045 USA

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Acufex Iso-Pac Labeling

Tyvek Pouch Lid Acufex Iso-Pac

ACUFEX

ISO - PAC
CRUCIATE ACCESORY KIT
STERILE

CONTENTS ARE STERILE UNTIL
PACKAGE IS DAMAGED OR BROKEN

NOTE: FEDERAL (USA) LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN

SINGLE USE ONLY. DO NOT RESTERILIZE.

CONTENTS:

CLEAR-TRAC CANNULA	SUTURE RETRIEVER	CANNU-FLEX GUIDE WIRE	DRILL TIP GUIDE WIRE
CANNULATED BONE TUNNEL PLUG	ISOTAC	ISOTAC PILOT WIRE	SPADE TIP PASSING PIN

ACUFEX MICROSURGICAL, INC.
MANSFIELD, MA 02045 USA

Product Identification Label Acufex Iso-Pac

ACUFEX

CAT. NO. XXX	1 KIT
--------------	-------

ISO - PAC
CRUCIATE ACCESSORY KIT
STERILIZED BY GAMMA IRRADIATION

LOT NO. XXXXXX	401XXX
----------------	--------

Box Label Acufex Iso-Pac

STERILE

CONTENTS ARE STERILE
UNTIL PACKAGE IS DAMAGED OR BROKEN

NOTE: FEDERAL (USA) LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN

SINGLE USE ONLY. DO NOT RESTERILIZE.

ACUFEX MICROSURGICAL, INC.
MANSFIELD, MA 02045 USA

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Acufex Iso-Pac Product Insert

ISOTAC®

WARNING: This device is not intended for permanent fixation. The Isometry tack must be securely tethered by an intact, undamaged #2 suture. The Isotac is a sterile product which can only be used once.

1. Perform an appropriate notchplasty and gain excellent arthroscopic exposure of the proposed ACL attachment site.
2. Use of the ACL Tibial Guide to drill a tibial tunnel from an external point 20-25 mm below the joint line, entering the joint at the tibial anatomic attachment site.
3. Pre-drill an insertion point for the Isotac (proposed Isometric site) with a 2.0 mm trocar tip K-wire.
4. Approximate the Isometric site on the femur and pre-drill the site with a 2.0 mm trocar tip K-wire.
5. Thread eye of tack with a #2 non-absorbable suture and pass suture through Isotac Cannulated Driver using Acufex® Suture Retriever.
6. With Driver inserted through tibial tunnel, screw Isotac into the insertion point under arthroscopic view.
7. Remove Driver. Pass suture through the appropriate size centering plug and through Acufex Isometric Positioner in one step.
8. Insert plug and Isometric Positioner into place.
9. With knee at approximately 45° flexion, lock Isometer to 0 position, take up slack in sutures and secure them to the Isometer.
10. Unlock Isometric Positioner. Put knee through range of motion while observing calibrations on the Isometric Positioner. An optimal reading reveals 0 to 1 mm change in length while flexing and 2 to 3 mm elongation (tightening) in terminal extension.
11. If reading is unacceptable, remove Isotac by first repassing sutures through the Cannulated Driver before unscrewing Isotac and repeat steps 3 through 10.

Acufex Microsurgical, Inc.

130 Forbes Boulevard
Mansfield, MA 02048
(508)339-9700
(800)45ACUFEX

©Acufex Microsurgical, Inc. 1991

393016 REV A

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DEC. 7

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7. Device Description

The device(s) submitted under this Premarket notification are a combination of products which are currently being marketed individually, sold non-sterile, or in sets of different components sold sterile and/or non-sterile. Acufex intends to market this combination of instruments and tools as a set, sold sterile for the convenience of the surgeon. These kits are provided in two configurations, both available sterile, for single use.

Both package configurations contain the identical base set of accessories found in the Acufex Pro-Pac, in addition the Acufex Iso-Pac also includes a Suture Retriever, a Isotac, and the accompanying Isotac Pilot Wire.

The Acufex Pro-Pac and Iso-Pac are surgical kits containing sterile instruments, guide(s), and accessories for general surgical / orthopedic use. Each instrument, guide or accessory has a particular use in the operating room. The intended use, description, and specifications for each part of this kit are described individually.

1. Acufex Drill Tip Guide Wire

Intended Use:

The wire is used to pre-drill bone tunnels and guide the placement of instruments and accessories used in arthroscopic surgery.

Description:

The drill tip guide wire consists of a stainless steel wire, with a fluted end.

Specifications

Dimensions: 2.4 mm x (11 to 15)mm

Materials: Stainless Steel 316 LVM, meeting ASTM Standard F 138.

2. Acufex Passing Pin

Intended Use:

The Acufex Passing Pin is a surgical wire used to pre-drill bone tunnels endoscopically. An eyelet in the pin allows for sutures to be drawn and passed through drilled bone tunnel.

Description:

The passing pin is a stainless steel wire with fluted tip. The tip enables the surgeon to pre drill bone tunnels. A recessed eyelet found in the pin is used for threading sutures, allowing for the drawing (passing) of suture through the bone tunnel.

Specifications

Dimensions: 2.4 mm x Range(11" - 15")

Material: Stainless Steel 17-4PH, meeting the ASTM Standard F899-84 for Stainless Steel used in surgical instruments.

3. Acufex Cannulated Bone Tunnel Plug

Intended Use:

The Acufex bone tunnel plug is a short cannula used to help control fluid loss while providing a sealed instrument portal during arthroscopic procedures.

Description:

The Acufex Bone Tunnel Plug has a tapered, ringed shaft and a two stage seal, which allows instruments to access the portal. The 55 mm shaft is constructed of a polypropylene elastomer, the seal is constructed of gum rubber. The seal prevents excessive fluid loss during an arthroscopic procedure.

Specifications

Dimensions: 5 mm x 55 mm

Materials:

Shaft: Krayton (Thermoplastic Elastomer and Polypropylene)
Seal: Gum Rubber

All of the materials meet USP Class VI test standards for biocompatibility.

4. Acufex Clear-Trac™ Cannula and Obturator

Intended Use

The Acufex Clear Trac Cannula is a straight clear plastic cannula used as an instrument portal during arthroscopic procedures. The clear plastic construction provides visualization of instruments that are introduced through the cannula.

Description

The cannula is constructed of a clear PVC shaft with a gum rubber seal. The cannula can be used to introduce a number of hand held surgical instruments used in arthroscopic procedures. The cannula has a seal to prevent fluid extravasation, and an obturator used to keep the cannula clear while inserting into an arthroscopic portal.

Specifications

Diameter: .038 in
Length(Range): 7 mm - 9mm

Materials:

Shaft: Poly Vinyl Chloride (PVC 2212RRM-118)
Seal: Gum Rubber
Obturator: Polystyrene

These materials meet USP Class VI test standards for biocompatibility.

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5. Acufex Cannu-Flex™ Guide Wire

Intended Use

The Cannu-Flex Guide Wire is a surgical wire used to guide the placement of cannulated instruments and accessories in an arthroscopic surgical procedure.

Description

The Acufex Cannu-Flex Guide Wire is constructed of Nitinol, a nickel titanium alloy widely used in the medical device industry. The use of this alloy allows for a unique flexibility of the wire, which resists kinking.

Specifications

Dimensions: .045 " x 9 "

Materials: Nitinol meeting USP Class VI test for biocompatibility.

6. Acufex Isotac® & Pilot Wire

Intended Use

The Isotac is an isometric positioning tack used to aid in determining the isometric placement of a bone tunnel. The Pilot Wire is an accessory allowing for precise threading of a pilot hole of correct dimensions for the Isotac positioning tool.

Description

Both the Isotac and accessory Isotac Pilot Wire are stainless steel positioning tools. The pilot wire aids the surgeon by driving a pilot hole to maximize engagement of the Isotac isometric positioning tack. The Isotac is manually engaged in the pilot hole and used in conjunction with an Isometric measuring gauge to measure correct isometry in ligament replacement surgery. After Isometric measurement the Isotac is removed from the pilot hole and discarded.

Specifications

Dimensions

Isotac: .4"

Isotac Pilot Wire: .12 " x 9 "

Materials:

Isotac and Isotac Pilot Wire: 17-4 PH stainless steel, meeting the ASTM Standard F899-84 for stainless steel used in surgical instruments.

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7. Acufex Suture Retriever

Intended Use

The Acufex suture retriever is a disposable manual surgical instrument for general use intended to snare and pass suture.

Specifications

Length: 280 mm

Materials:

Outer Tube: 304 stainless steel, AMS 5639 hypo tubing

Inner Tube: Nitinol hypo tubing

Snare Loop: Nitinol, crimped into inner tube

Spring: 302 stainless steel, AMS 5688 spring temper

Handle: Lexan polycarbonate resin

All of these materials meet USP Class VI test standards for biocompatibility.

Product drawings for each individual component included in these kit(s) follow. The individual component drawings are number, following the description numbers above, for your convenience.

All materials used for each part / accessory in the Pro-Pac and Iso-Pac are constructed of materials which are widely used in the medical device industry. They are generally regarded as safe for use by health care professionals.

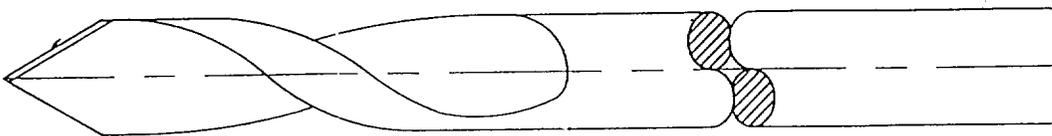
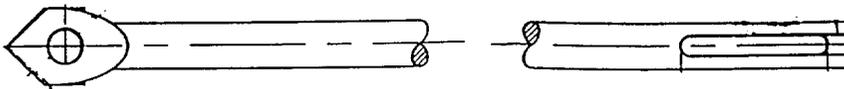
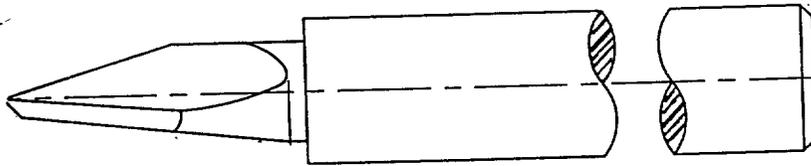
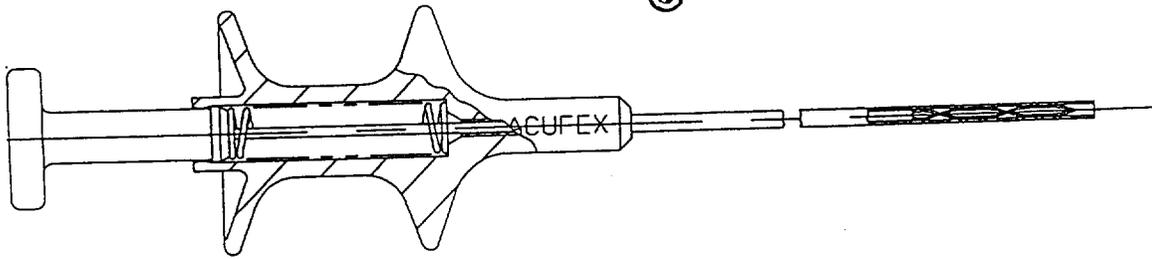
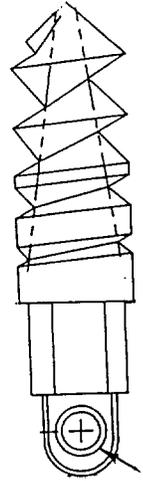
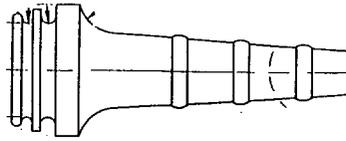
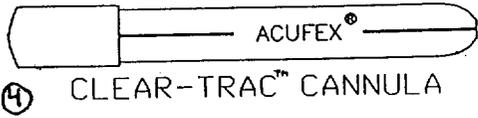
Packaging and Sterilization

The Pro-Pac and Iso-Pac instruments and accessories are packaged together in a double blister thermoformed PETG tray, with a Tyvek seal. The tray is enclosed in a SBS product box.

The Iso-Pac and Pro-Pac are sterilized by Gamma Irradiation. The sterilization parameters for these kits are described below:

Sterilization Method:	Gamma Irradiation
Dose:	2.5 mRad (minimum) - 4.0 mRad (maximum)
Validation Method:	Applicable AAMI guidelines for gamma irradiation
SAL:	10 ⁻⁶
Pyrogenicity:	Non-pyrogenic. Determined by the Limulus Amebocyte Lysate (LAL) procedure for the detection and quantifications of endotoxins

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8. Substantial Equivalence

The Acufex Pro-Pac and Iso-Pac are kits containing devices which are all currently marketed either separately, or sold non-sterile by Acufex Microsurgical, Inc. Acufex intends to market these kits as sterile products for the convenience of the surgeon. Each component of these kits is identical to the individually currently marketed product, and is currently available separately, or are sold as Non-Sterile only.

The currently marketed products sold by Acufex, and the products respective 510K number, if applicable, are summarized below.

Instrument	510K Number
Acufex Cannulated Bone Tunnel Plug	K925437
Acufex Clear-Trac Cannula	K920454
Acufex Suture Retriever	K926036 (Pending)
Acufex Drill Tip Guide Wire	Class I Exempt
Acufex Passing Pin	Class I Exempt
Acufex Cannu-Flex Guide Wire	Class I Exempt
Acufex Isotac Pilot Wire	Class I Exempt
Acufex Isotac	Class I Exempt

Each component is similar in design, materials, or function of these currently marketed products. Each device (accessory or instrument) is similar in function, materials, and intended use to other devices currently marketed by other companies.

The intent of this product is to market a set of components, currently marketed separately, as a sterile single use convenience package. The component parts of these sets are all currently marketed by Acufex.

A summarized comparison of the components to this pack, and the currently marketed products follows. A current Acufex catalog describing the individual substantially equivalent components found in the kits, as well as the product insert for the Isotac is attached.

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<u>Properties</u>	<u>Pro-Pac Component</u>	<u>Substantially Equivalent Component</u>
Indication Size Material Labeling Sterilization	Acufex Cannulated Bone Tunnel Plug Arthroscopic Surgery Instrument Portal 5 mm x 55 mm Krayton, Gum Rubber Seal Sterile, Single Use. Gamma Irradiation	Acufex Cannulated Bone Tunnel Plug K925437 Arthroscopic Surgery Instrument Portal 5 mm x 55 mm Krayton, Gum Rubber Seal Sterile, Single Use. Gamma Irradiation
Indication Size Material Labeling Sterilization	Acufex Clear-Trac Cannula Arthroscopic Surgery Instrument Portal 7mm and 9mm Alpha PVC 2212RRM-118, Gum Rubber Seal, Polystyrene Obturator Sterile, Single Use. Gamma Irradiation	Acufex Clear-Trac Cannula K920454 Arthroscopic Surgery Instrument Portal 7mm and 9mm Alpha PVC 2212RRM-118, Gum Rubber Seal Sterile, Single Use. Gamma Irradiation
Indication Size Material Labeling Sterilization	Acufex Drill Tip Guide Wire Arthroscopic Surgical Wire 2.4 mm x 11 mm Stainless Steel 316 LVM Sterile, Single Use. Gamma Irradiation	Acufex Drill Tip Guide Wire Arthroscopic Surgical Wire 2.4 mm x 11 mm Stainless Steel 316 LVM Non-Sterile Not Applicable
Indication Size Material Labeling Sterilization	Acufex Passing Pin Surgical Wire for Passing Suture 3 mm x (11 to 15)mm Stainless Steel 17-4PH Sterile, Single Use. Gamma Irradiation	Acufex Passing Pin Surgical Wire for Passing Suture 3 mm x (11 to 15)mm Stainless Steel 17-4PH Non-Sterile Not Applicable
Indication Size Material Labeling Sterilization	Acufex Cannu-Flex Guide Wire Arthroscopic Surgical Wire, Guide Wire 9 in. x .045 in. Nitinol Non-Sterile Gamma Irradiation	Acufex Cannu-Flex Guide Wire Arthroscopic Surgical Wire, Guide Wire 9 in. x .045 in. Nitinol Non-Sterile Not Applicable

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Properties	Iso-Pac(Additional) Component(s)	Substantially Equivalent Component(s)
Indication Size Material Labeling Sterilization	Acufex Isotac Pilot Wire Accessory Instrument for Isotac 9" 17-4 PH Stainless Steel Sterile, Single Use Gamma Irradiation	Acufex Isotac Pilot Wire Accessory Instrument for Isotac 9" 17-4 PH Stainless Steel Non-Sterile Not Applicable
Indication Size Material Labeling Sterilization	Acufex Isotac Positioning Template Tool .4" 17-4 PH Stainless Steel Sterile, Single Use Gamma Irradiation	Acufex Isotac Positioning Template Tool .4" 17-4 PH Stainless Steel Sterile, Single Use Gamma Irradiation
Indication Size Material Labeling Sterilization	Acufex Suture Retriever Surgical Suture Snare 280 mm Stainless Steel, Nitinol, Lexan Sterile, Single Use Gamma Irradiation	Acufex Suture Retriever K926036 Surgical Suture Snare 280 mm Stainless Steel, Nitinol, Lexan Sterile, Single Use Gamma Irradiation

Additional substantially equivalent products include various surgical kits. These kits are similar in design, function, and materials to the Acufex Pro-Pac and Iso-Pac. The surgical kits are a compilation of orthopedic surgical instruments sold sterile, as a set for the convenience of the surgeon. These substantially equivalent surgical kits are summarized in the table below. Catalogues and product information for these substantially equivalent surgical kits follows.

Substantially Equivalent Product	Labeling and Use	Materials
ACUFEX Uni-Cut Carpal Tunnel Release Kit K922557	Sterile, Single Use Only Orthopedic Surgery Instrument Kit	17-4 PH Stainless Steel, Lexan
FlexMedics Meniscal Suture Needle Kit	Sterile, Single Use Only Orthopedic Surgery Instrument Kit	Nitinol, Plastic
Dyonics Arthroscopic Knives K894728	Sterile, Single Use Only Orthopedic Surgery Instrument Kit	Stainless Steel, Plastic
Dyonics Arthroscopic Acromioplasty Surgi-Pak K893136	Sterile, Single Use Only Orthopedic Surgery Instrument Kit	Stainless Steel, Thermoplastic

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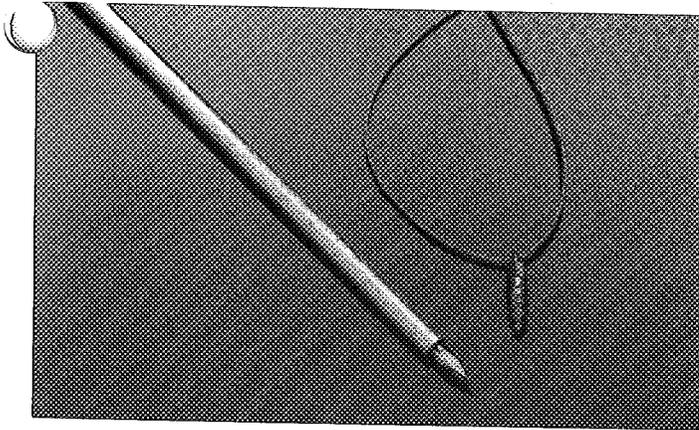
**Acufex Product Catalog
Substantially Equivalent Product**

38

Fixation Buttons
Isometric Positioner
Isotac[®]
Eccentric Tibial Guide
Suture Retriever
Guide Wires
Passing Pins
Tendon Leaders
Suture Passers
Drill Bits
Tendon Strippers
Rasps
Gouges
Curettes

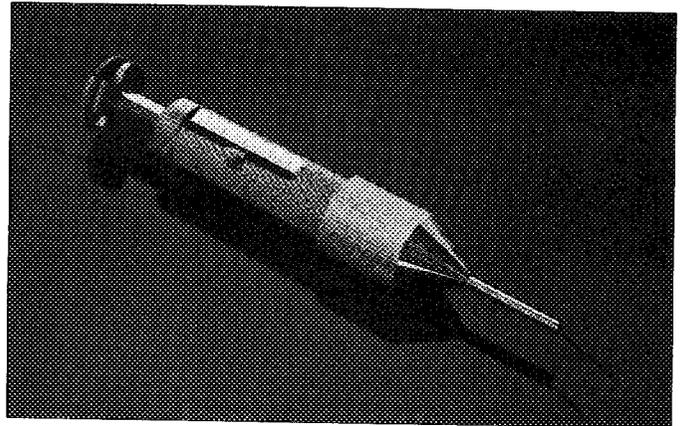
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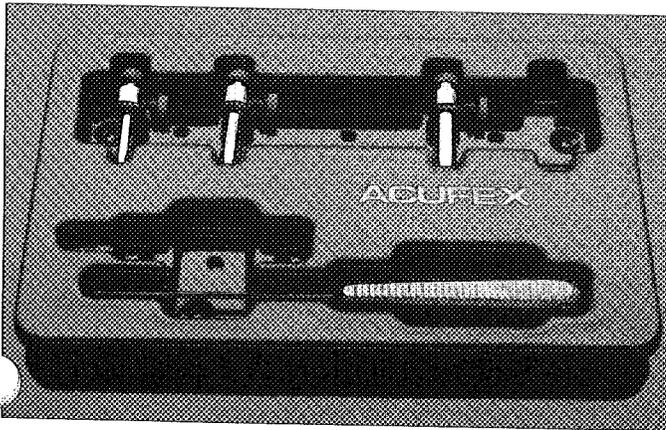
◀ **Isotac® Pilot Wires** simplify isometric measurement by allowing the surgeon to drill a precise pilot hole for the Isotac, matching its size and geometry. Precise pre-drilling maximizes Isotac thread engagement.

Part #013619 (Box of 6)



▲ **Isometric Positioner** assists the surgeon in determining the precise isometric position of the proposed ACL graft – before the full-sized tunnel is drilled. Efficient to use without disrupting the standard K-wire drilling procedure, the Isometric Positioner measures ligament excursion in millimeters at proposed ACL tunnel sites.

Part #013580



▲ **Isotac® Kit** allows the surgeon to easily determine the precise isometric tunnel placement. It may be used with any ACL guide currently on the market.

Part #013581

Isotac Kit

Part #013583

Isotac (Box of 6/Sterile)

Part #011635

Isotac Kit Tray

Eccentric Tibial Guides (not shown) allow accurate isometric measurement at the perimeter of the proposed tibial attachment site.

Small (7-8mm)

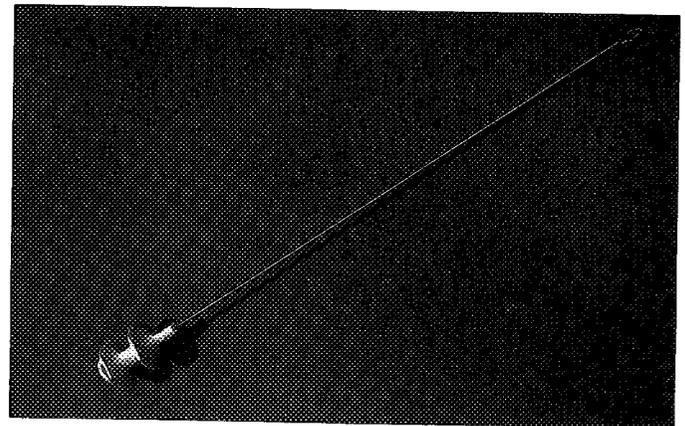
Part #013507

Medium (9-10mm)

Part #013508

Large (10mm and larger)

Part #013509



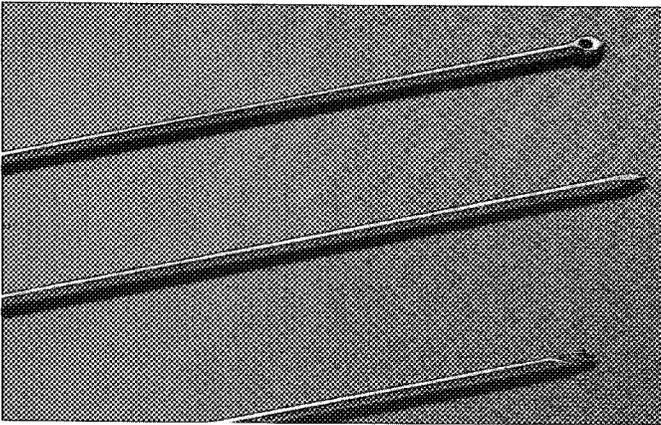
▲ **Suture Retriever**, a unique spring-loaded retractable snare, allows for ultimate control when passing suture through K-wire tunnels or the cannulated shaft of the Isotac Driver or Isometric Positioner.

Suture Retriever (Sterile/Disposable)

Part #013593 (Box of 6)

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020



▲ **Spade Tipped Passing Pins** facilitate the drilling of K-Wire tunnels for easy passing of sutured grafts. **2.4mm Passing Pins** with 10° trocar tips enable the surgeon to accurately pre-drill tibial and femoral tunnels. The large recessed eyelet facilitates suture passage in graft placement. **2.4mm Drill Tip Guide Wires** minimize skiving, even against hard cortical bone. They are ideal for pre-drilling tunnels.

- 3mm Spade Tip Passing Pins Part #013110 (Box of 6)
- 4mm Spade Tip Passing Pins Part #013111 (Box of 6)
- 2.4mm Passing Pins Part #013658 (Box of 6)
- 2.4mm Drill Tip Guide Wires Part #013978 (Box of 6)

▼ **.045" Guide Wires** (not shown) are designed to assure parallel guidance. Single trocar tip.

Stainless Steel Guide Wires

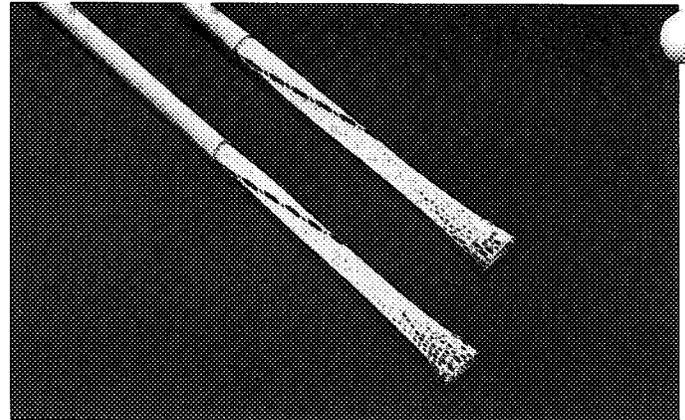
- .045 x 9 inch Part #013442 (Box of 6)
- .045 x 12 inch Part #013443 (Box of 6)

Cannu-Flex™ guide wires (not shown) feature a unique memory alloy construction which resists kinking and straighten after bending.

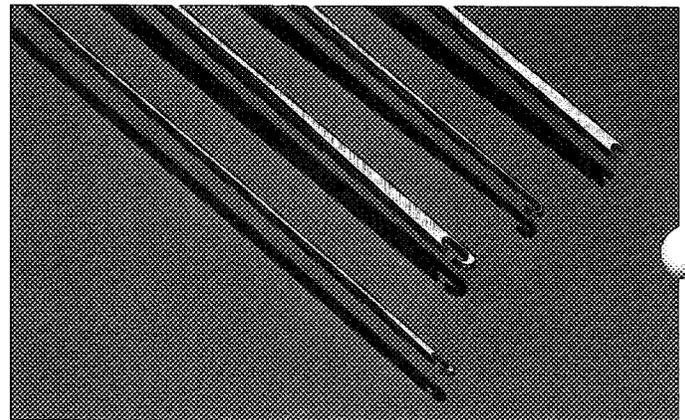
- .045 x 9 inch Part #013475 (Box of 6)

► **Fixation Buttons** are specifically designed to secure sutures attached to the tendon graft. These high-strength buttons are designed with a low profile for patient comfort.

- Part #013635 14mm Fixation Button
(Box of 6/Sterile)
- Part #013636 17mm Fixation Button
(Box of 6/Sterile)



▲ **Tendon Leaders** pull replacement grafts through bone tunnels, compressing the graft to allow easier passage.
Part #013590 (Sterile/Box of 5)



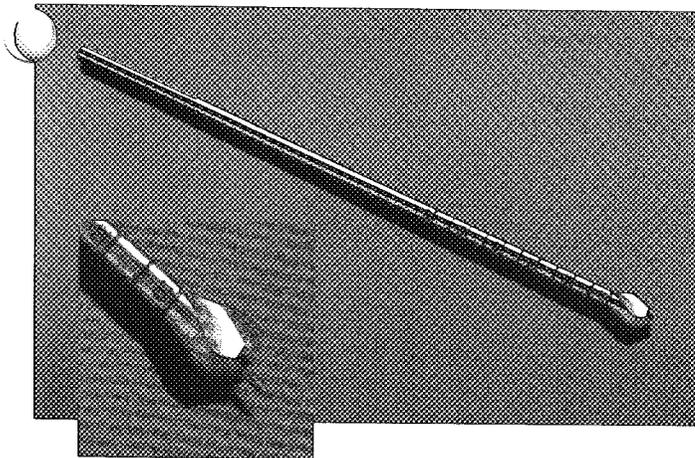
▲ **Suture Passers** are convenient tools to pull sutures through the K-wire tunnels and the Acuflex Isometric Positioner.

- Suture Passer, Pusher Part #013556
- Suture Passer, Hook Part #013555
- Suture Passer, Crochet Part #013557
- Suture Passer, 1.8mm Crochet Part #013558



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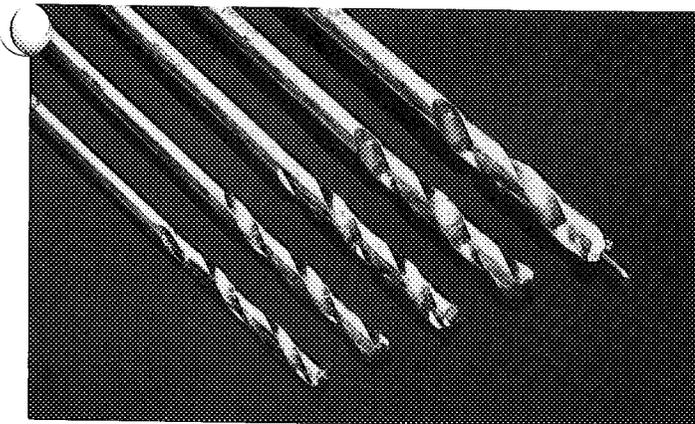
41



◀ **Endoscopic Cannulated Drill Bits** afford the surgeon maximum maneuverability in drilling, which is especially important when making a femoral tunnel through an already-drilled tibial tunnel (Endoscopic Technique). The tapered shaft tip allows for atraumatic drilling, and the calibrations facilitate precise monitoring of tunnel depth.

5mm	Part #013498
6mm	Part #013499
7mm	Part #013660
8mm	Part #013661
9mm	Part #013662
10mm	Part #013663
11mm	Part #013664
12mm	Part #013665
13mm	Part #013666

▼ **Cannulated Drill Bits** used to overdrill a K-wire, are available in 1mm increments, ranging from 6mm to 14mm, to allow a precise graft/tunnel fit. The sharp tip and large flutes facilitate the evacuation of bone chips, reducing the possibility of thermal necrosis, without the time-consuming back and forth motion required with a cannulated reamer.

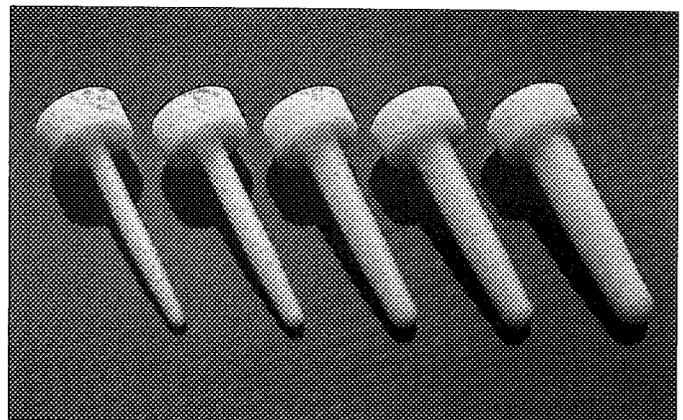


▼ **Bone Tunnel Plugs** are available in five sizes to ensure the secure tunnel fit needed to maintain distension throughout the ACL procedure.

Comprehensive Set (3S, 3M, 3L, 3XL, 3XXL)	Part #013592
Set (3L, 3XL, 3XXL)	Part #013589
Set (3S, 3M, 3L)	Part #013563

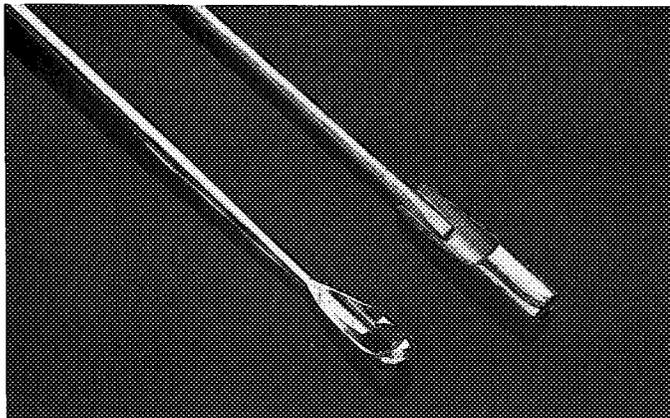
6mm	Part #013542
7mm	Part #013543
8mm	Part #013544
9mm	Part #013545
10mm	Part #013546
11mm	Part #013547
12mm	Part #013548
13mm	Part #013549
14mm	Part #013551

Also available: combination sets of 6-14mm cannulated drill bits and sizing tubes.



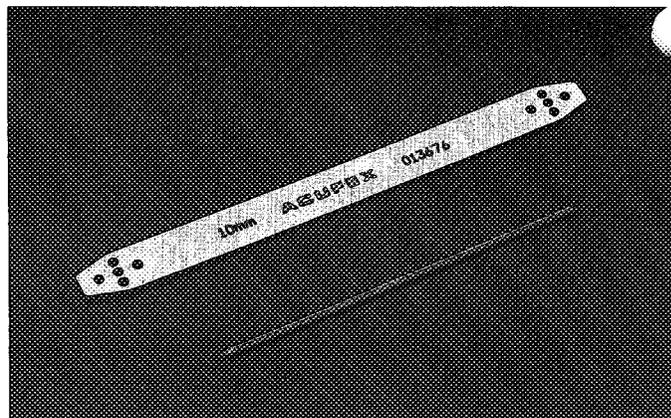
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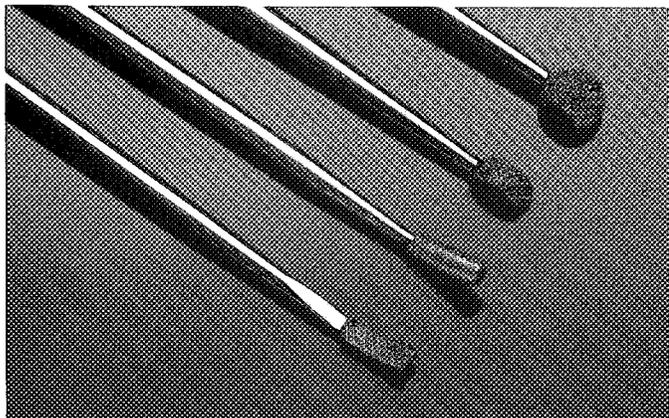
▲ **Closed Tendon Stripper** is extra long and reinforced for subcutaneous stripping of the semitendinosus tendon. **Slotted Tendon Stripper** allows continuous attachment of the distal end of semitendinosus tendon during stripping.

Closed Tendon Stripper	Part #013550
Slotted Tendon Stripper	Part #013554



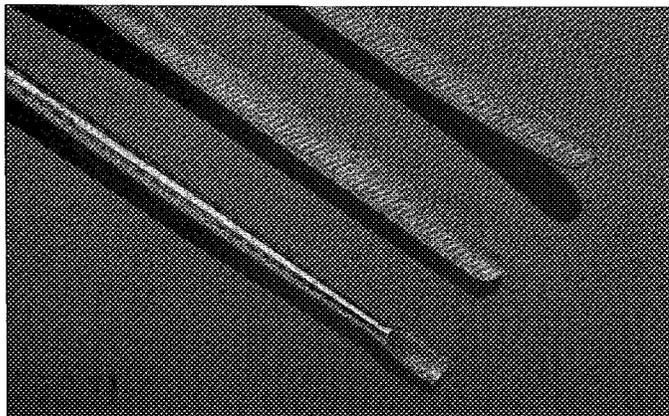
▲ **Patellar Tendon Templates** quickly and easily allow precise sizing and cutting of the patellar graft.

Part #013678	Patellar Template Set (includes 9, 10, and 11mm templates and pins)
Part #013669	Patellar Template Pins (replacement, Box of 6)



◀ **Chamfering Rasps** help minimize graft abrasion by enabling the surgeon to chamfer tunnels cleanly and precisely. These lightweight rasps are small and slim to fit through standard arthroscopic portals and tunnels. **The Chamfering Rasp** has a long convex curve with retrograde cutting ability. **The Half Round Rasps** feature a half ball with sharp diamond teeth which allow multidirectional cutting. **The Bone Tunnel Rasp** delivers a uniquely controlled cut which quickly and precisely cleans off soft tissue and bone while chamfering a tunnel.

8mm Half Round Rasp	Part #013571
7mm Half Round Rasp	Part #013572
Bone Tunnel Rasp	Part #013569
Chamfering Rasp	Part #013570



◀ **Arthroscopic Notchplasty Gouges** accurately demarcate and effectively remove notch fragments to help minimize impingement.

Arthroscopic Notchplasty Gouge (Curved)	Part #012724
Arthroscopic Notchplasty Gouge (Straight)	Part #012725
Compound Gouge	Part #012702

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ACUFEX[®]

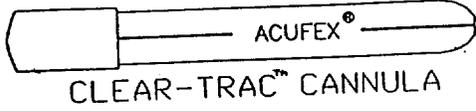
The Standard in Arthroscopic Technology

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800-45-ACUFEX (800-452-2833)
FAX: 508/339-8853
TELEX: 924474

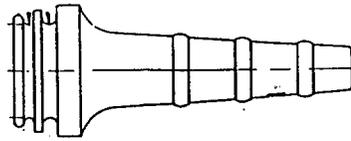
European Marketing Representative
Crown House
Hornbeam Square North
Harrogate HG 2 8PB England
TEL: 0423879379
FAX: 0423873202

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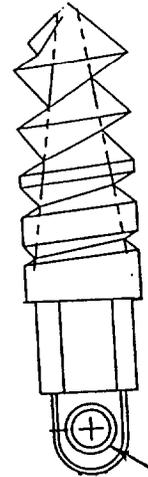
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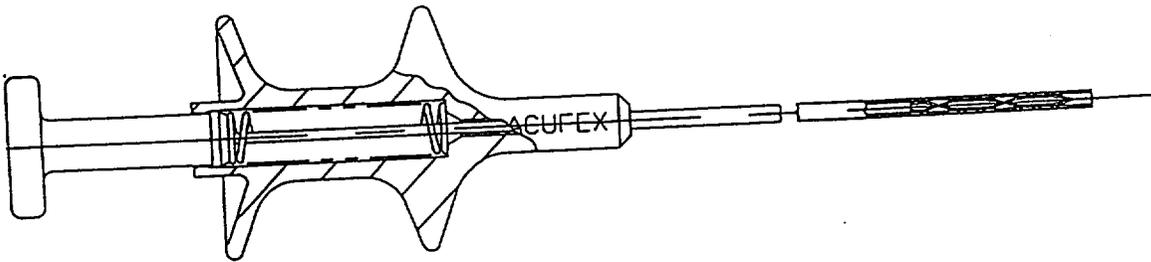
CLEAR-TRAC™ CANNULA



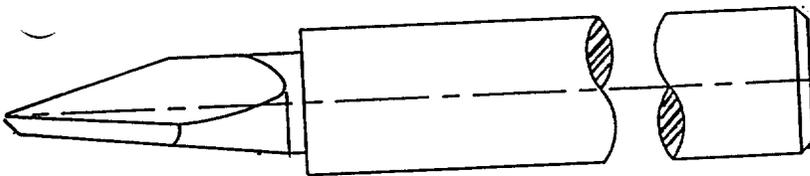
FLEXIBLE CANNULATED BONE TUNNEL PLUG



ISOTAC

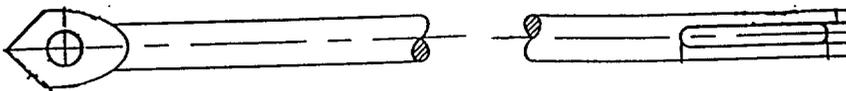
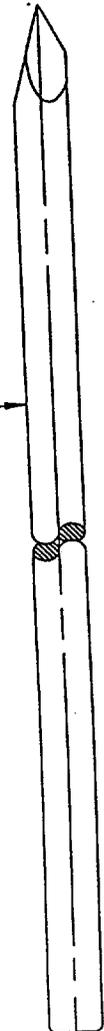


SUTURE RETRIEVER

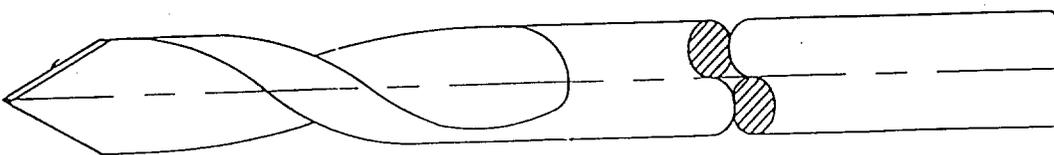


ISOTAC PILOT WIRE

CANNU-FLEX GUIDE WIRE



PASSING PIN



GUIDE WIRE

Isotac Product Insert

ISOTAC®

WARNING: This device is not intended for permanent fixation. The Isometry tack must be securely tethered by an intact, undamaged #2 suture. The Isotac is a sterile product which can only be used once.

1. Perform an appropriate notchplasty and gain excellent arthroscopic exposure of the proposed ACL attachment site.
2. Use of the ACL Tibial Guide to drill a tibial tunnel from an external point 20-25 mm below the joint line, entering the joint at the tibial anatomic attachment site.
3. Pre-drill an insertion point for the Isotac (proposed Isometric site) with a 2.0 mm trocar tip K-wire.
4. Approximate the Isometric site on the femur and pre-drill the site with a 2.0 mm trocar tip K-wire.
5. Thread eye of tack with a #2 non-absorbable suture and pass suture through Isotac Cannulated Driver using Acufex® Suture Retriever.
6. With Driver inserted through tibial tunnel, screw Isotac into the insertion point under arthroscopic view.
7. Remove Driver. Pass suture through the appropriate size centering plug and through Acufex Isometric Positioner in one step.
8. Insert plug and Isometric Positioner into place.
9. With knee at approximately 45° flexion, lock Isometer to 0 position, take up slack in sutures and secure them to the Isometer.
10. Unlock Isometric Positioner. Put knee through range of motion while observing calibrations on the Isometric Positioner. An optimal reading reveals 0 to 1 mm change in length while flexing and 2 to 3 mm elongation (tightening) in terminal extension.
11. If reading is unacceptable, remove Isotac by first repassing sutures through the Cannulated Driver before unscrewing Isotac and repeat steps 3 through 10.

Acufex Microsurgical, Inc.

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393016 REV A

**ACUFEX Uni-Cut Carpal Tunnel Release Kit (K922557)
Substantially Equivalent Product**

48

The light at the end of carpal tunnel syndrome.

After years of extensive research and development, Acuflex unveils *Uni-Cut*, the most advanced endoscopic technique for relieving carpal tunnel syndrome.

With its unique dual-channelled cannula, *Uni-Cut* is light years ahead of the competition. While one channel of the cannula houses the endoscope for viewing the transverse carpal ligament, the other guides the probing and cutting instruments through the area of dissection. This permits single portal entry for minimal invasiveness. The cannula's semi-closed tip reduces the possibility of overextending the cutting field. And, distal to proximal dissection further safeguards against the risk of neurovascular damage.



In short, *Uni-Cut* gives you more control without sacrificing full visualization of the entire procedure.

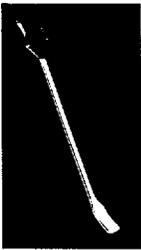
Designed in conjunction with Terrence R. Orr, M.D., South Lake Tahoe, California

Uni-Cut Carpal Tunnel Release Kit A disposable set of precision instruments.

Kit Elements



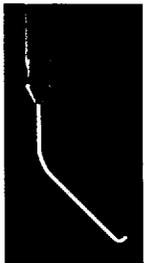
Dual channelled Cannula
Acuflex's unique cannula houses a 2.7mm diameter 30° endoscope while it guides the hook-tip knife, permitting full visualization of the entire cutting procedure.



Elevator
Used to bluntly dissect the bursal tissue from the deep surface of the transverse carpal ligament.



Channeler
6.5mm and 10mm diameter ends, used to dilate a path to aid the entry of the cannula, reducing soft tissue trauma and to verify release of the ligament respectively.



Probe
Used to palpate the under surface of the ligament and to identify and control the distal margin of the transverse carpal ligament.



Hook Knife
The unmatched sharp Edge® designed to cut from distal to proximal safeguarding neurovascular tissue.



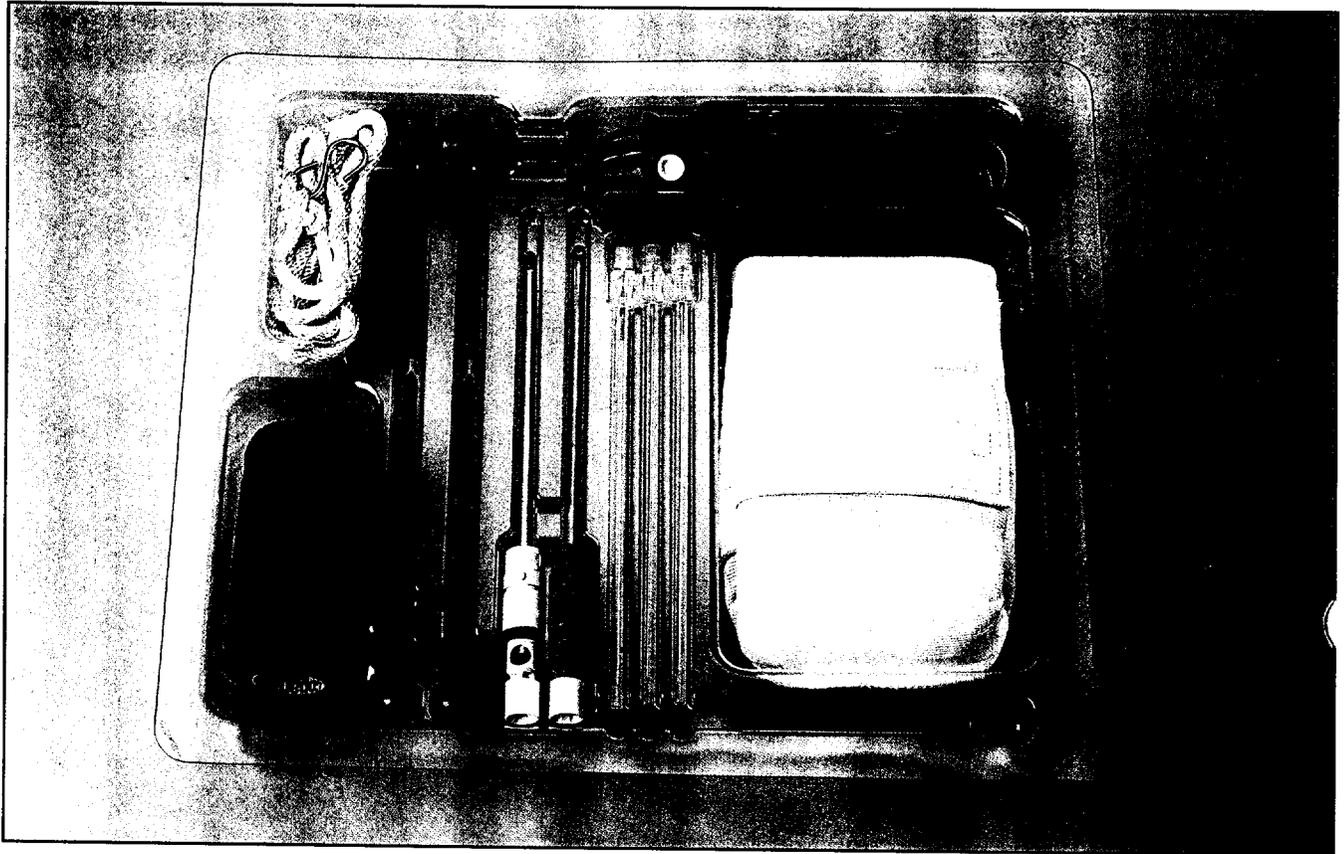
As with all instruments designed by Acuflex, *Uni-Cut* meets our high standards for quality, sharpness and precision. For more information about *Uni-Cut* — the logical, straight forward approach to carpal tunnel release — call Acuflex today at 1-800-452-2833.

**Dyonics Arthroscopic Acromioplasty Surgi-Pak (K893136)
Substantially Equivalent Product**

50

Arthroscopic Acromioplasty Surgi-Pak

Quality Disposable Instrumentation for Arthroscopic Acromioplasty



- **Sterile pre-assembled tray minimizes set-up time and ensures availability of all disposable instrumentation required for arthroscopic acromioplasty**
- **Single-use disposables reduce clean-up time and eliminate the need for expensive resterilization procedures**
- **Procedure-specific kit:**
 - reduces need for stocking multiple individual items simplifying inventory control
 - consolidates multiple chargeable items into a single patient-charge unit
- **High quality disposable components offer maximum convenience and ensure superior performance and safety**
- **Kit includes:**
 - 4.0mm Acromionizer Blade
 - 5.5mm Full Radius Blade
 - 5.5mm Plastic Inflow Cannula
 - 5.5mm Plastic Operative Cannulas (2)
 - 5.5mm Plastic Trocar
 - 5.5mm Plastic Obturator
 - Electrocautery Probe with Insulated 90° Tip and Push-button Probe Holder
 - Shoulder Suspension Kit
 - 18 ga. x 6" Spinal Needles (3)

Smith & Nephew Dyonics Inc.
90 Duxbury Road, Andover, MA 01810 U.S.A.
Call: (978) 476-1313
(In Massachusetts: 978-476-2000)

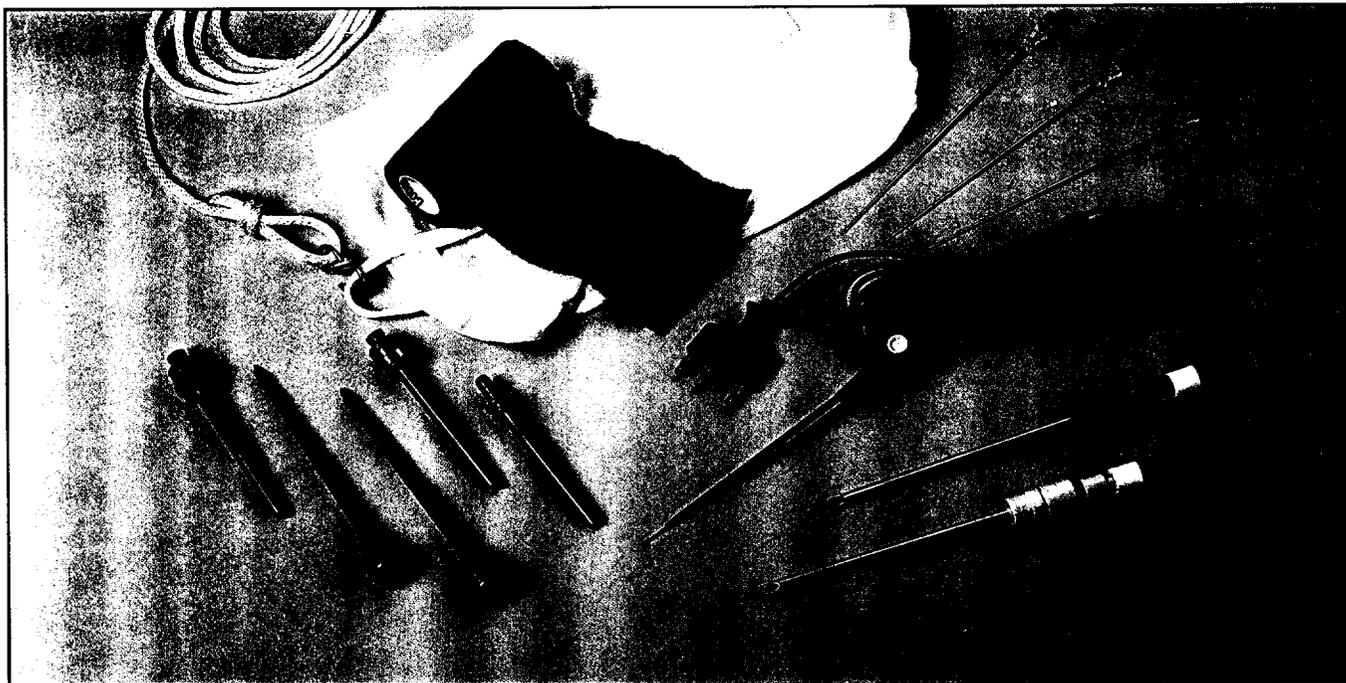
Smith & Nephew

DYONICS

... Shoulder Arthroscopic Instrumentation for the '90s

Arthroscopic Acromioplasty Surgi-Pak

Quality Disposable Instrumentation for Arthroscopic Acromioplasty



A. 4.0mm Acromionizer Blade

The elongated burr design provides superior access for rapid resection and smooth contouring of the acromion. The 4.0mm size provides aggressive, controlled bony tissue resection.

B. 5.5mm Full Radius Blade

The large cutting window permits rapid, efficient soft tissue removal.

C. Insulated Electrocautery Probe with Pushbutton Probe Holder

The Teflon® sleeve ensures optimal insulation even at high temperatures. The insulated

probe can be used in saline eliminating the need for time-consuming joint flushing. The 90° tip angle facilitates access to the coracoacromial ligament. The pushbutton probe holder is compatible with all generators that have a three-prong receptacle.

D. 5.5mm Non-conductive Plastic Cannula Sets

Plastic cannulas are safe for use with electro-surgical devices. A fluid seal in the operative cannulas prevent fluid backflow. This promotes optimal joint distention and reduces splashing for a safer operative environment. Inflow

cannula provides the optimal flow rate for enhanced joint visualization. A 5.5mm trocar (sharp) and a 5.5mm obturator (blunt) are supplied for cannula placement.

E. Shoulder Suspension Kit

Designed to safely suspend the arm by distributing pressure over the forearm to minimize impingement of the radial nerve. Sterile packaging allows the versatility of application either before or after scrubbing.

F. Spinal Needles 18ga. x 6"

The three stainless steel needles are convenient for landmark identification.

Ordering Information

Catalog Number	Product Description
3720	Arthroscopic Acromioplasty Surgi-Pak Sterile, Disposable

Smith & Nephew Dyonics Inc.

160 Dascomb Road, Andover, MA 01810 U.S.A.
Call Toll Free 1-800-343-5717
(In Massachusetts 508-470-2800)

Smith+Nephew



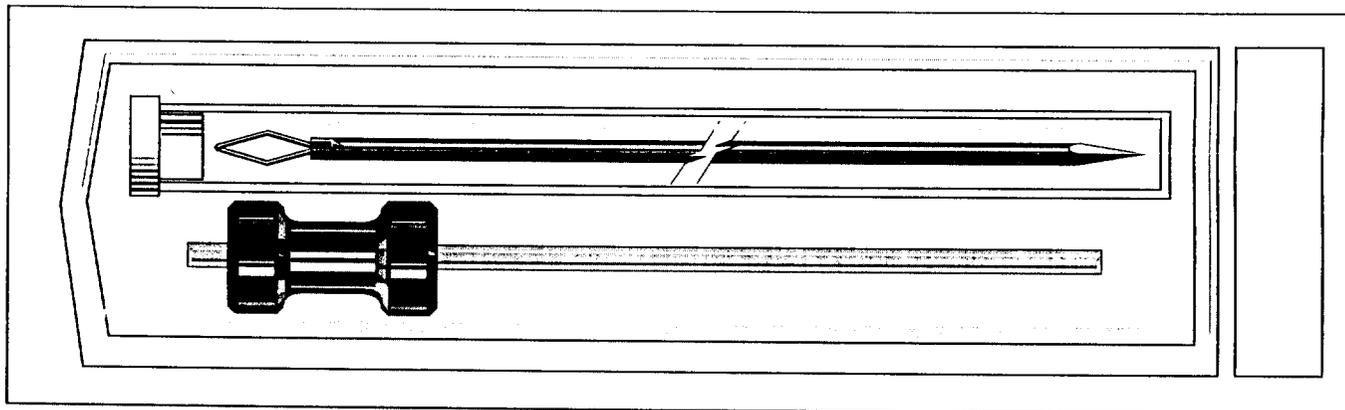
**FlexMedics Meniscal Suture Needle Kit
Substantially Equivalent Product**

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Nickel-Titanium Meniscal Suture Needle Kit

Our new clinically tested, advanced design meniscal needles offer many clinical advantages over standard stainless steel needles.



Special Clinical Benefits

- Made from superelastic Nitinol, more resistant to bending.
- More predictable needle path, for precise tip placement.
- Requires less pushing force than stainless steel needles.
- Hand-Formable Cannula, no special tools required.
- Trocar style tip, retains sharp cutting edge.
- Flexible suture attachment, easy to thread.

Ordering Information

Product Number	Diameter		Length	
	Inches	Millimeters	Inches	Millimeters
200002	.029	740	10	254
200003	.032	812	10	254

Each kit contains one Nitinol needle and one cannula in a sterile package.



4 54

**Dyonics Arthroscopic Knives (K894728)
Substantially Equivalent Product**

Smith+Nephew



D i s p o s a b l e s

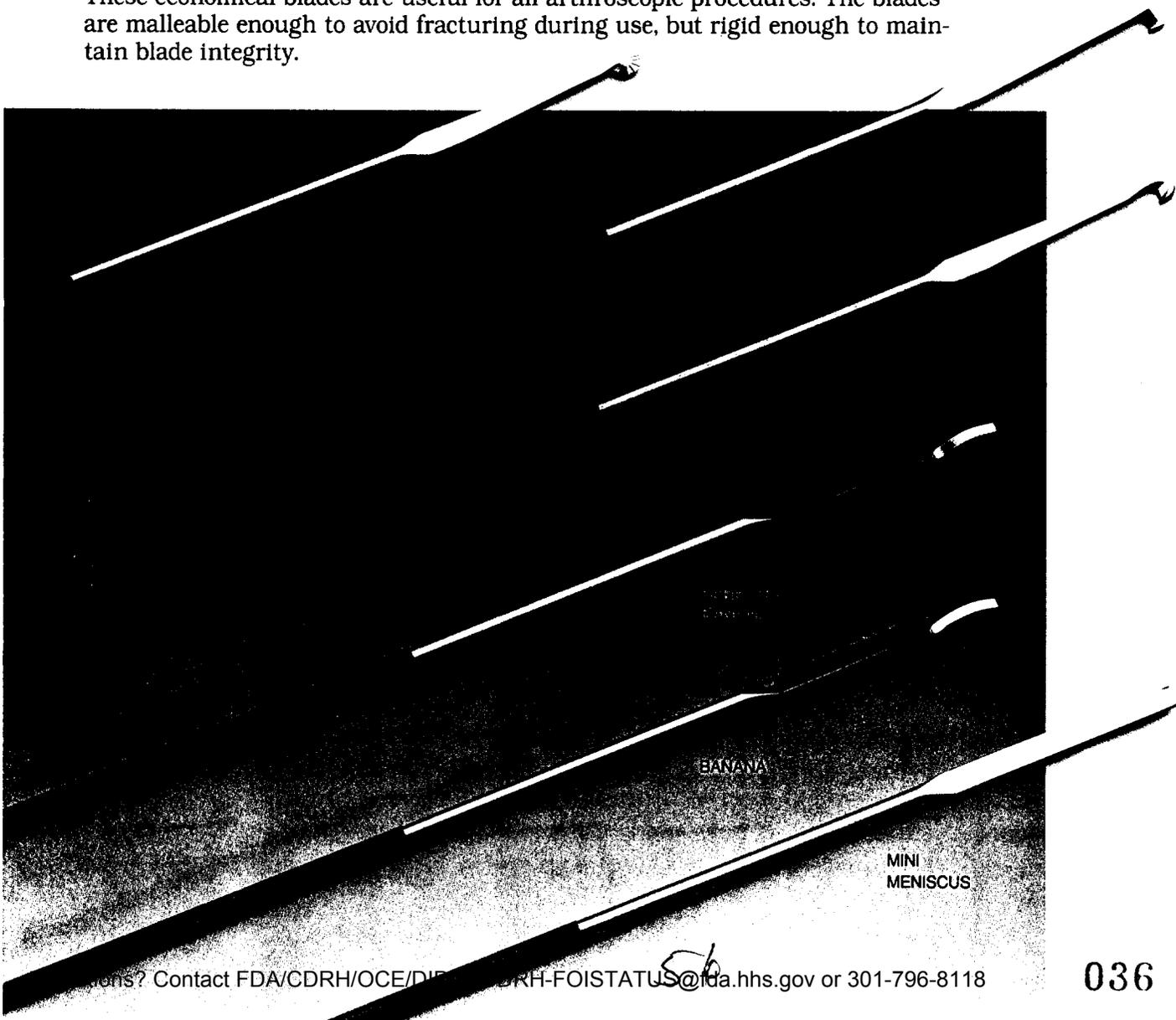
ARTHROSCOPIC KNIVES CONSISTANT, SAFE, CONVENIENT.

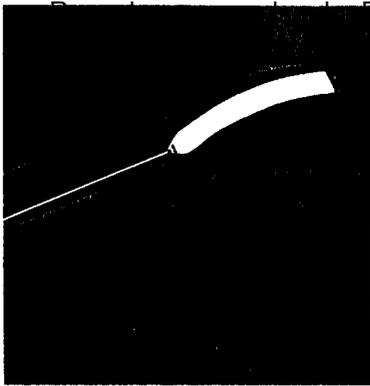
Now, consistent performance and disposable convenience are available in a selection of knives from the arthroscopy leader—Smith & Nephew Dyonics.

- Pre-sterilized, to save time
- Malleable blades—safer, resist breaking
- Disposable—saves time and maintenance
- Single-use, to ensure convenience and safety
- Plastic coated handles, for a sure grip
- One-piece, to ensure safety

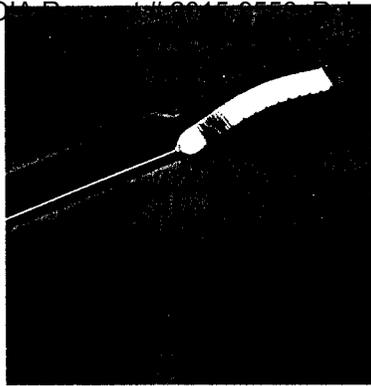
Six blade styles are available, allowing you to choose the most effective cutting style for each procedure. Each blade fits through cannula 4 mm and larger. The long, straight handles allow removal of the cannula, allowing added flexibility of movement.

These economical blades are useful for all arthroscopic procedures. The blades are malleable enough to avoid fracturing during use, but rigid enough to maintain blade integrity.





Cat. No. 3554 Banana



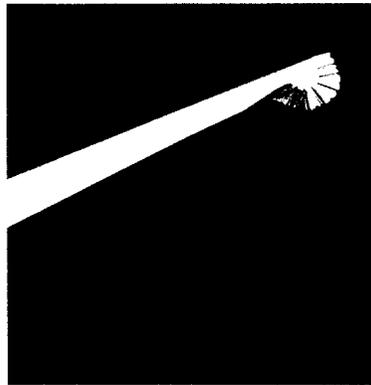
Cat. No. 3555 Serrated Banana



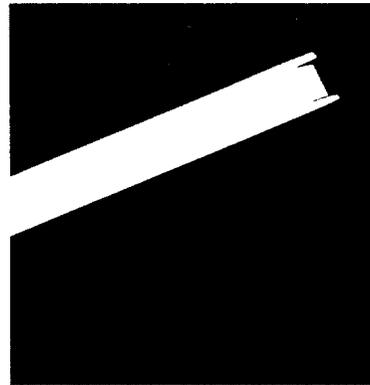
Cat. No. 3556 Retrograde



Cat. No. 3557 Hook



Cat. No. 3558 Rosette



Cat. No. 3559 Mini Meniscus

DISPOSABLE ARTHROSCOPIC KNIVES

Packaging

Each knife is individually packaged, sterile, in a blister tray with peel-back Tyvek® lid. Six identical knives are packaged in a dispenser box.

Sterilization

These instruments are sterile and intended for single-use only, and should not be resterilized.

Warranty

Smith & Nephew Dyonics products are guaranteed to be free from defects in material and workmanship.

Tyvek is a registered trademark of
E. I. duPont de Nemours & Company

Smith & Nephew Dyonics Inc.

160 Dascomb Road, Andover, MA 01810 U.S.A.
Call Toll Free 1-800-343-5717
(In Massachusetts 508-470-2800)

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SEC. 9

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9. 510K Statement -Availability of Safety and Effectiveness Information

In accordance with the Safe Medical Devices Act of 1990, Acufex Microsurgical, Inc. will make available all information included in this premarket notification regarding the safety and effectiveness of the Acufex Pro-Pac and Iso-Pac Surgical Accessory Kits that supports a finding of substantial equivalence. Any information deemed confidential or proprietary by Acufex will not be released.

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