



FEB 16 1990

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: K900070
Modified Uses of the
Arthroscopic Surgical
System
Regulatory Class: II
Dated: December 28, 1989
Received: January 4, 1990

Mr. Eric Bannon
Regulatory Affairs Manager
Dyonics, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Dear Mr. Bannon:

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 (Performance Standards) or class III (Pre-market 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 pre-amendments 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 Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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,

Carl A. Larson

Carl A. Larson, Ph.D.
Director,
Division of Surgical
and Rehabilitation Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Memorandum

From REVIEWER(S) - NAME(S) J. Parkhurst

Subject 510(k) NOTIFICATION K900070

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:

See Memo Record.

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-HRX (Class II)

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

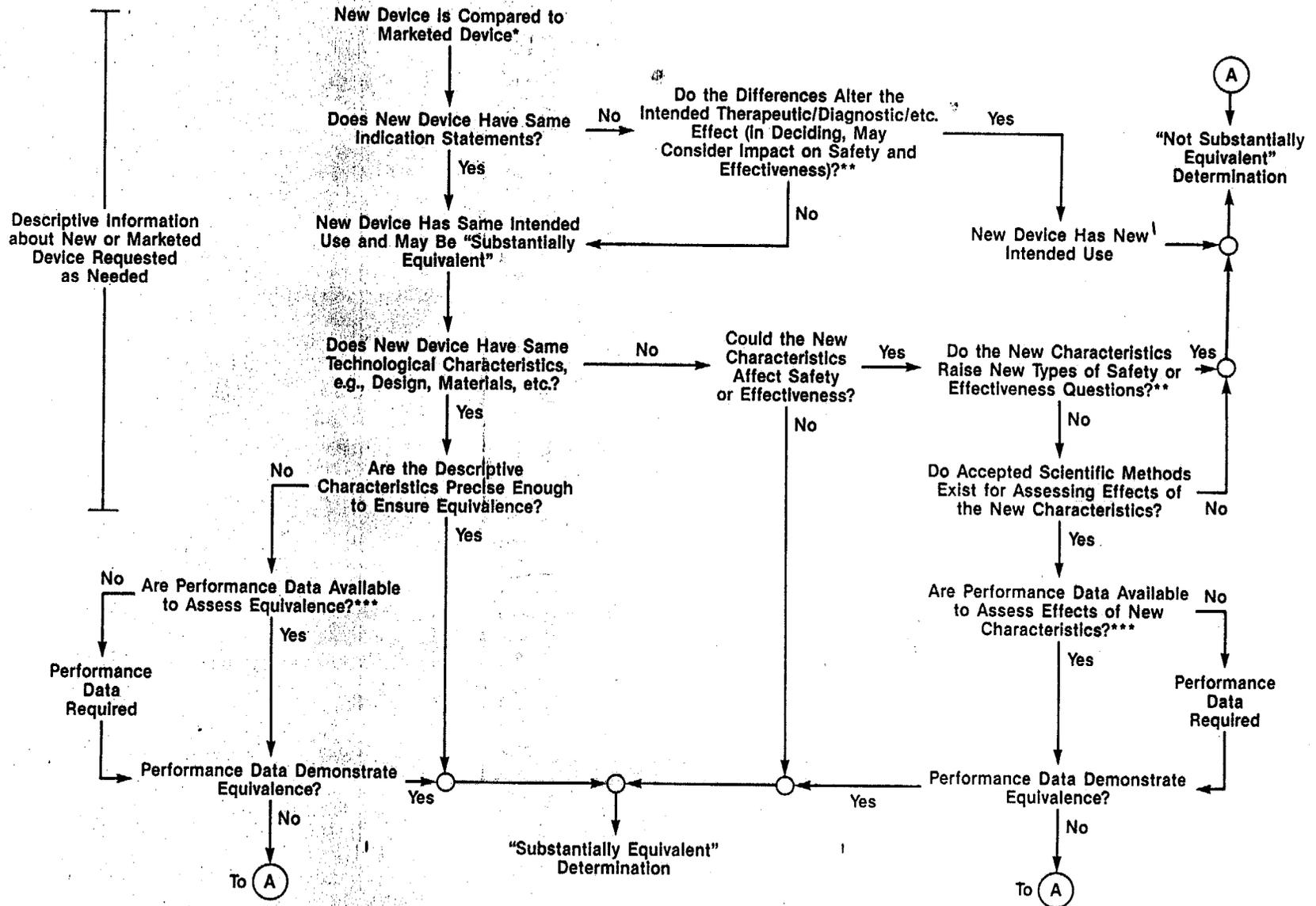
REVIEW: Daniel J. McSwain 2/7/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW: Thomas J. Callahan 2/15/90
(DIVISION DIRECTOR) (DATE)

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



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* 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.

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 2/7/90
FROM: Biologist	OFFICE ODE	
TO: File	DIVISION BSRD-RDB	
SUBJECT: K900020 - Modified Use of Arthroscopic Surgical System (Dyonics)		
<p>SUMMARY</p> <p>In the submission, Dyonics' intention is to modify the indications for use of their Arthroscopic Surgical System for use in the decompression of bulging discs in the lumbar region of the spine (L5-S1). The name of this modified system is the Simultaneous Arthroscopic Micro Discectomy System (PAMDS).</p> <p>The PAMDS consists of a cannulated introduction set with hard instruments, video discoscope set and a sterile disposable set. The <u>cannulated intro set/hard instruments</u> consists of a 18 G spinal needle (ASTM 304 - stainless steel) with stylette, .031" guide wire, cannulated tapered obturator (ASTM 316 - stainless steel), 3mm and 5mm trephine (ASTM 304 - stainless steel), Cup forceps (ASTM 304 - stainless steel), Dyo-Vac suction punch, magnetic retriever (304 stainless steel), forceps deflector tube and cannula insertion stop (304 stainless steel). The <u>video discoscope set</u> allows visualization of the disc area for procedural assessment and consists of a 2.7mm irrigation sheath and a video discoscope (2.7mm x 30°) ASTM 304 stainless steel. The <u>sterile disposable set</u> consists of a 4.5mm full radius arthroscopy blade (ASTM 304 L Stainless Steel).</p>		
SIGNATURE	BEST AVAILABLE COPY	DOCUMENT NO. 4

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 2/7/90
FROM:	OFFICE	
TO:	DIVISION	
SUBJECT:		

SUMMARY

~~and~~ a 4.5mm tubular arthroscopy blade (ASTM 304L stainless steel), and a tissue trap.

After I reviewed the labeling/instructions for use of the PAMDS some questions were raised. I spoke by phone with Eric Barron (Reg. Affairs Mgr.) at Dynnic to clarify my concerns and ~~the~~ obtained the following information: there is only one "incision" made on the patient ^{when using} the PAMDS (not two "incisions" as ^I initially thought); the arthroscope (videoscope) is used to periodically ~~to~~ view ~~the~~ the state of the procedure (in conjunction ~~also~~ with the use of roentgenograph + MRI).

I compared the PAMDS to the Nucleotome by Surgical Dynamics (K844131) which was found SE on Nov 29, 1984 and to the Kambin Spinal Instrument Set (K853678) found SE on Sept. 24, 1985.

I compared the introduction set/hard instruments and the disposable set of the PAMDS to the surgical

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MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 2/7/90
FROM:	OFFICE	
TO:	DIVISION	

SUBJECT:

SUMMARY

instruments of the predicate devices. The design + materials used in the PAMDS instruments raise no new safety + effectiveness concerns when compared to predicate devices.

In addition, I compared the video arthroscope used in the PAMDS to the Dyonics Arthroscope (K880150) found SE on March 4, 1988. Also the trimmer + full radius blades used in the PAMDS were compared to Dyonics Disposable Arthroscopy Blades (K8 33587) found SE on

Nov 14, 1983. The design + materials used to manufacture the blades are the same as predicate devices. The arthroscope used in the PAMDS is similar to predicate devices + raise no new safety + effectiveness concerns.

Based on the above findings, I find the Dyonics PAMDS to be SE to predicate devices.

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SIGNATURE <i>J. Parkhurst</i>	DOCUMENT NO. K90 0070 6
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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

JANUARY 8, 1990

DYONICS, INC.
ATTN: ERIC BANNON
160 DASCOMB ROAD
ANDOVER, MA 01810

D.C. Number : K900070
Received : 01-04-90
90th Day : 04-04-90
Product : MODIFIED USES OF
THE ARTHROSCOPIC
SURGICAL SYSTEM

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

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, 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,

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

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K900070

Dyonics, Inc., 160 Dascomb Road, Andover, Massachusetts 01810 (508) 470-2800 TWX 710-347-0337 FAX (508) 470-2193

FDA-COM-ODE

JAN - 4 1990

December 28, 1989

FOOD AND DRUG ADMINISTRATION
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Re: 510(K) Premarket Notification

Dear Sir/Madam,

As required by the Federal Food Drug and Cosmetic Act, Dyonics Incorporated hereby notifies you of our intent to modify the indications for use of our Arthroscopic Surgical System for use in the decompression of bulging discs in the lumbar region of the spine. The original system was reviewed by FDA under 510(K) submission K771218A with subsequent modifications reviewed under K8202367, K833587 and K880150. The name of the modified system is the Percutaneous Arthroscopic Micro Discectomy System.

The modified system consists of a cannulated introduction set, with hand instruments, video discoscope set and a sterile disposable set. The components of each set with a description and comparison to similar products already marketed is contained in Attachment A with pertinent literature.

Drawings of each component are contained in Attachment B.

Attachment C contains the final proposed classifications for each component.

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Attachment D is the proposed labeling for the set. This includes the following:

1. OUTER BOX LABEL: To be placed on all non-sterile products. The catalog number and description will change to reflect each component.
2. INSTRUCTIONS/PROCEDURE: Including indications, contradictions and procedural details.
3. STERILE BLADE LABEL: For each blade.

The Percutaneous Arthroscopic Micro Discectomy System proposed by Dyonics is similar to one currently marketed by Surgical Dynamics under the name Nucleotome (R); Automated Percutaneous Lumbar Discectomy. A copy of pertinent literature is attached as Attachment E. Attachment F is a collection of pertinent articles describing the surgical procedure intended for this product. Dyonics registration number is 1216828. If there are any questions please call me at, (508) 470-2800, Ext. 348.

Sincerely,



Eric Bannon
Regulatory Affairs Manager

EB/sh
89/05

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Attachment A: COMPONENT DESCRIPTIONS AND COMPARISONS TO SIMILAR PRODUCTS.

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Attachment A: PERCUTANEOUS ARTHROSCOPIC MICRO DISCECTOMY

- A. CANNULATED INTRODUCTION SET/HAND INSTRUMENTS: Instruments designed to provide access to the appropriate lumbar region for tissue removal. Contains the following components:
1. Spinal Needle: 18 gauge, 6" long with removeable stylette. This is similar to those contained in the Kambin spinal instrument set, marketed by Pilling and readily available from Popper and Sons, Inc. A copy of pertinent literature is attached. We intend to purchase this from Popper and Sons, Inc.
 2. Guide Wire: .031" approximately 25cm in length. This is similar to those contained in the Kambin spinal instrument set marketed by Pilling. We will purchase this as an OEM item.
 3. Cannulated Tapered Obturator: Approximately 5.5mm O.D. with an ID to slip fit over guide wire. Contains 1cm graduations. Similar to cannulated trocar contained in the Kambin spinal set marketed by Pilling. Current literature is attached.
 4. Universal working Cannula with Removeable Fluid Seal Adapter: With 1cm graduations. Removeable fluid seal adapter for fluid control. Will also be fitted with adjustable cannula insertion stop to control cannula insertion similar to cannula contained in Kambin spinal instrument set marketed by Pilling.
 5. 3mm, 5mm Trepine: 3mm, 5mm O.D. size to manually bore through annulus fibrosus. Similar to rotary cutters contained in Kambin spinal instrument set marketed by Pilling.
 6. Forceps Deflector Tube: To accept 2.5mm O.D. flexible tipped cup forceps. Proximal end to accept standard suction tubing. Similar to forceps deflector contained in Kambin spinal instrument set marketed by Pilling.
 7. Tissue Removal Rod/Magnetic Retriever Rod: Sized to slip fit through 5.0mm Trepine to push out trapped tissue. Similar to Kambin tissue removal rod and magnetic retriever rod. Marketed by Pilling. We plan on purchasing this item from Instrument Makar.
 8. Cup Forceps: 2.5mm Flexible; Designed for use in conjunction with forcep deflector tube for manual cutting and removal of nucleus material posterior to site of fenestration. Similar to those marketed by Pilling in the Kambin spinal instrument set.

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9. 2mm Angled up, 3mm Straight Cup Forceps: Manual cutting instruments used in conjunction with universal cannula for removal of nucleus and annulus material. Both are similar to those in the Kambin spinal instrument set marketed by Pilling.
10. Dyo-Vac Suction Punch: 3.5mm: Hand cutting instrument properly tooled to allow for suction to be applied proximal. This is similar to those marketed by Dyonics since 1974. Pertinent literature is attached.

These components will be accompanied by a storage/sterilization.

- B. Video Discoscope Set: To allow visualization of the disc area for procedural assessment. Contains the following components.
1. 2.7mm Irrigation Sheath: Designed to fit inside the working cannula. Fitted with single stopcock to allow tubing connection for suction. Similar to cannulas used as accessories to arthroscopes and powered surgical systems for arthroscopic surgery. These were reviewed by FDA under 510(K) K771218A, K820367, K880150. Pertinent literature is attached.
 1. Video Discoscope: 2.7mm x 30 degree scope for visualization of disc area, to be used in conjunction with video. This is similar to arthroscopes marketed by Dyonics since 1972. These were also reviewed by FDA under K771218, K820367, K880150. Pertinent literature is attached.

This set will also be accompanied by a storage/sterilization tray.

- C. Sterile Disposable Set: These represent the only components which will be sterile, one time use disposable products. They will be packaged individually.
1. 4.5mm Trimmer Blade 4.5 Full Radius Blade: For use with Dyonics powered surgical instruments. Similar to other disposable blades reviewed by FDA under 510(K) K833587. Will be packaged in PETG Thermoformed Blister and sealed with 1073 Tyvek(R) lid. Dyonics literature on disposable blades and powered instruments is attached.
 2. Tissue Trap: Offered as an accessory to provide a means of collecting tissue for pathological purposes. Placed within suction tubing line. Similar to those marketed by Filtertek. Pertinent literature is attached.

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PILLING

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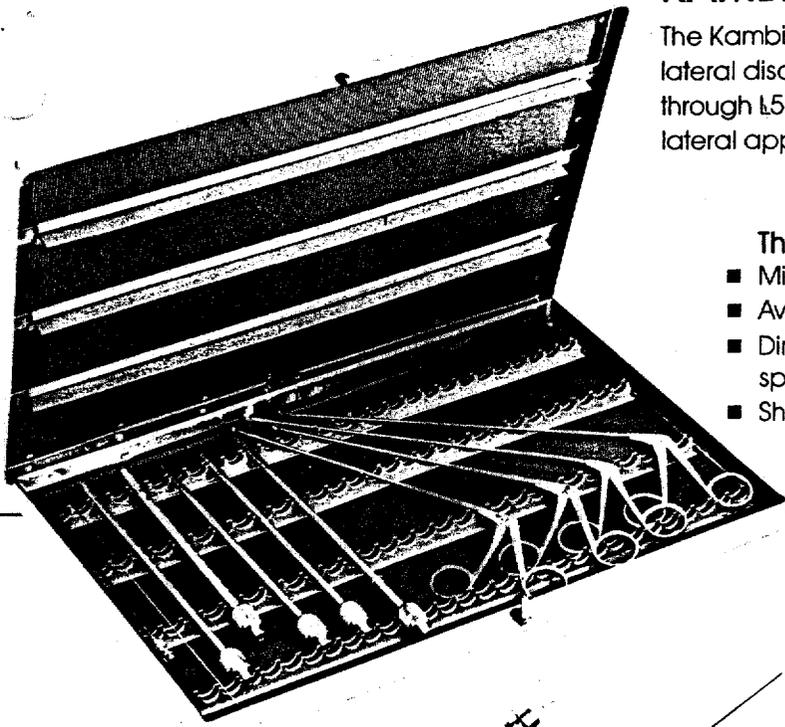
KAMBIN SPINAL INSTRUMENT SET

The Kambin Spinal Instrument Set, when used for percutaneous lateral discectomy*, facilitates surgical decompression of the L3 through L5 herniated lumbar discs, using a percutaneous posterior lateral approach.

This technique has the advantages of:

- Minimal morbidity
- Avoids epidural bleeding and scarring
- Directs any possibility of future reherniation outside of the spinal canal
- Shortened hospital stay

*Covered by U.S. Patent No. 4,573,448



53-1000 Complete Kambin spinal set.
Includes 42-9602 sterilizing tray

53-1005 K-wire, .031" dia. x 9" long

53-1001 Spinal needle, 18 gauge,
6" long with stylet

53-1010 Blunt cannulated trocar, 18
cm. long with removable
Luer Lok fitting

53-1015 Cannula, 6.5 mm.
O.D., 4.9 mm. I.D. x 15
cm. with removable
Luer Lok fitting

53-1020 Rotary cutter, 3 mm.
diam. with perma-
nently attached Luer
Lok fitting

53-1022 Rotary cutter, 5 mm.
diam. with perma-
nently attached Luer
Lok fitting

53-1030 Forceps deflector tube for
use with flexible forceps
53-1036

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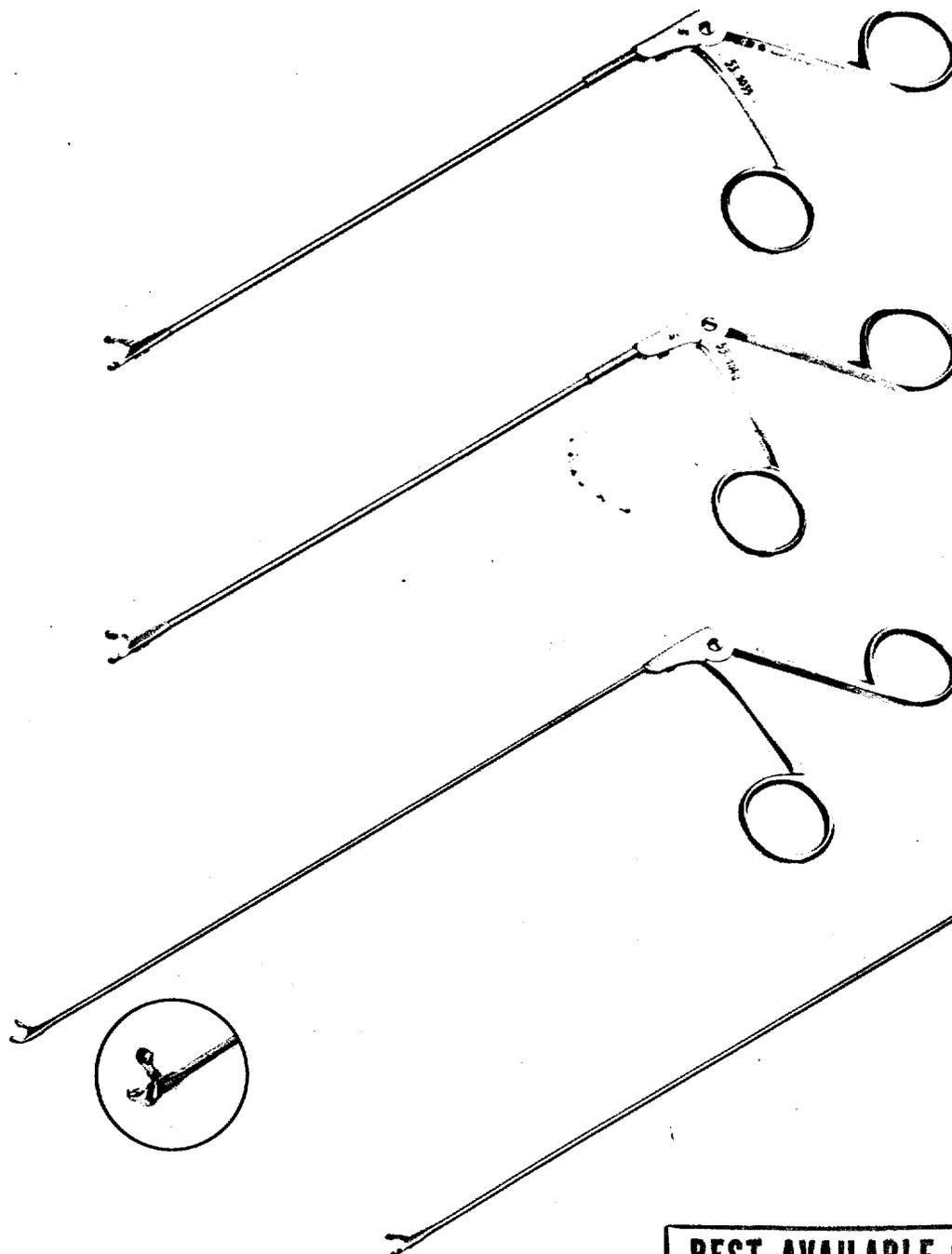
Unique characteristics of the technique include:

- Large fenestration of the annulus will not be blocked by tissue fragments and provides continuing decompression following completion of procedure.
- Diversity of instrumentation allows reaching posteriorly into the site of the herniation. The flexible forceps, deflector sheath, and angled forceps allow tissue removal in an area much larger in diameter than the 4.9 mm. inside diameter of the working cannula. This is not possible with straight probe systems which limit tissue removal to working channel diameter near the center of the disc.
- Patented suction technique moves fragmented material to the center of the disc for simple evacuation through the cannula.

- Local anesthetic allows communication with the patient during surgery and adds to safety of procedure.
- After effects on patient are minimal.
- Guide wire insertion technique makes sequential use of other instruments in the series simple and safe.

Caution concerning flexible forceps:

The flexible forceps is 4 cm. longer than the other forceps in the set. It is designed to be used inside the deflector. *Utilization of the flexible forceps without the deflector may be hazardous.*



53-1035 Kambin 3 mm. cup forceps, rigid, straight

53-1040 Kambin 4 mm. cup forceps, rigid, straight

53-1050 Kambin 2 mm. cup forceps, rigid, angled upward

53-1036 Kambin 2.5 mm. cup forceps, flexible. Use only with 53-1030 deflector tube.

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ORDERING INFORMATION

ITEM NO.	CATALOG NO.	DESCRIPTION
1.	53-1000	Complete Kambin spinal set, consisting of items 2 through 13 below
2.	53-1001	Spinal needle, 18 gauge, 6" long, with stylet
3.	53-1005	K-wire, .031" diam. x 9" long
4.	53-1010	Blunt cannulated trocar 18 cm. long with removable Luer Lok fitting
5.	53-1015	Cannula, 6.5 mm. O.D., 4.9 mm. I.D. x 15 cm. with removable Luer Lok fitting
6.	53-1020	Rotary cutter, 3 mm. diam. with permanently attached Luer Lok fitting
7.	53-1022	Rotary cutter, 5 mm. diam. with permanently attached Luer Lok fitting
8.	53-1035	Kambin 3 mm. cup forceps, rigid, straight
9.	53-1040	Kambin 4 mm. cup forceps, rigid, straight
10.	53-1050	Kambin 2 mm. cup forceps, rigid, angled upward
11.	53-1030	Forceps deflector tube for use with flexible forceps 53-1036
12.	53-1036	Kambin flexible 2.5 mm. cup forceps. Use only with 53-1030 deflector tube
13.	42-9602	Instrument storage and sterilizing tray, 10" x 15"

ACCESSORIES

14.	53-1060	Kambin tissue removal rod for 3 mm. rotary cutter
15.	53-1065	Kambin tissue removal rod for 5 mm. rotary cutter
16.	53-1070	Kambin magnetic retriever rod

Note: Items 2 through 7 are normally used in the sequence listed.

BIBLIOGRAPHY

- | | |
|---|---|
| <p>1. Kambin, Parviz and Harris Gellman. "Lateral Discectomy of the Lumbar Spine." <u>Clinical Orthopaedics</u>, April, 1983, Vol. 174.</p> <p>2. Kambin, Parviz and Steven Sampson. "Postlateral Percutaneous Suction-Excision of Herniated Lumbar Intervertebral Discs: Report of Interim Results." <u>Clinical</u></p> | <p><u>Orthopaedics</u>, June, 1986, Vol. 207.</p> <p>3. Kambin, Parviz and Steven Sampson. "Laminectomy Versus Percutaneous Lateral Discectomy: A Comparative Study." <u>Orthopaedic Transactions. The Journal of Bone and Joint Surgery</u>, Fall, 1984, Vol. 8.</p> |
|---|---|

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To order call our Customer Service Department or contact your Pilling representative at our toll free numbers 800-523-6507 (outside Pa.) or 800-492-2387 (Pa. only).
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PILLING

PRICE LIST
JANUARY 1987

KAMBIN™ SPINAL SET FOR PERCUTANEOUS LATERAL DISCECTOMY*

A new method for decompressing herniated intervertebral discs in the lumbar region

<u>CATALOG #</u>	<u>DESCRIPTION</u>	
53-1000	<u>COMPLETE KAMBIN™ SPINAL SET</u>	\$2,425.00
	Consists of:	
53-1001	Spinal needle, 18 gauge, 6" long with stylet	\$20.00
53-1005	K-wire, .031" diameter x 9" long	\$6.00
53-1010	Blunt Cannulated Trocar, 18 cm long with removable Luer Lok fitting	\$205.00
53-1015	Cannula, 6.5 mm O.D., 4.9 mm I.D. x 15 cm with removal Luer Lok fitting	\$210.00
53-1020	Rotary Cutter, 3 mm diameter with permanently attached Luer Lok fitting	\$225.00
53-1022	Rotary Cutter, 5 mm diameter with permanently attached Luer Lok fitting	\$230.00
53-1035	Kambin 3 mm Cup Forceps, rigid, straight	\$390.00
53-1040	Kambin 4 mm Cup Forceps, rigid, straight	\$392.00
53-1050	Kambin 2 mm Cup Forceps, rigid, angled upward	\$275.00
53-1030	Forceps Deflector Tube for use with flexible forceps 53-1036	\$225.00
53-1036	Kambin Flexible Cup Forceps, 2.5 mm (Use only with 53-1030 Deflector Tube)	\$334.00
42-9602	Instrument Storage and Sterilizing Tray 10" x 15"	\$211.00

ACCESSORIES

53-1060	Kambin Tissue Removal Rod for 3 mm Rotary Cutter	\$50.00
53-1065	Kambin Tissue Removal Rod for 5 mm Rotary Cutter	\$50.00
53-1070	Kambin Magnetic Retriever Rod	\$60.00

*Covered by U.S. Patent No. 4,573,448

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420 DELAWARE DRIVE P.O. BOX 7514 FORT WASHINGTON, PENNSYLVANIA 19034 215-643-2600 800-523-2579
TELEX 6711330 CABLE: SURGICAL—FORT WASHINGTON FAX 215-646-0340

Surgical Equipment and Supplies for Arthroscopy

'89 Catalog



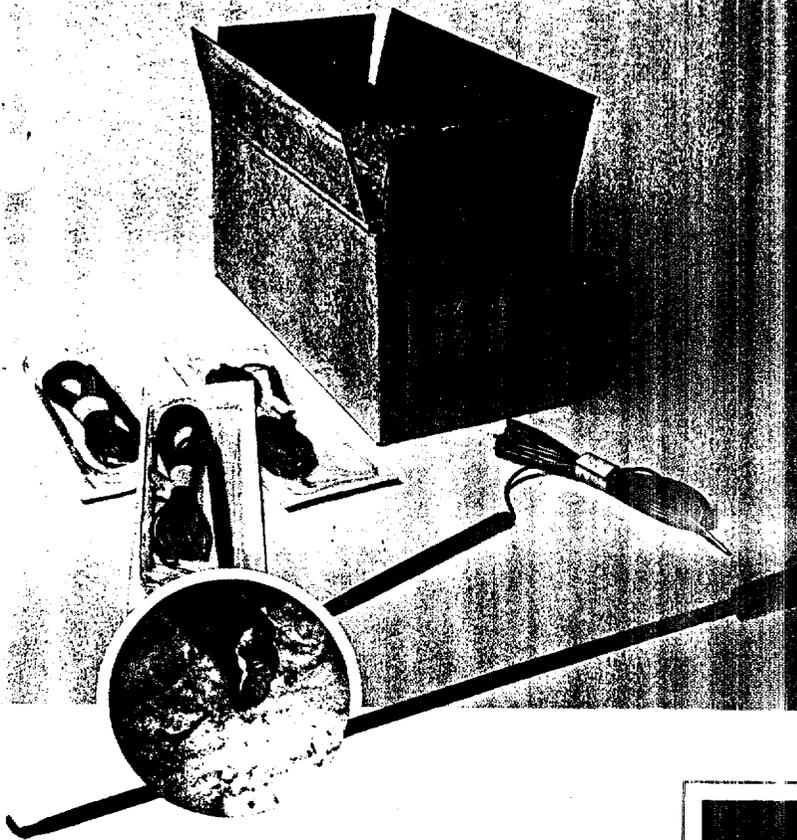
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1-800-248-4668
In Michigan 1-800-678-3434
Local (517) 332-3593
FAX (517) 332-2043

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CB

INSIDE:
New Products
and Services

IM Coagulators fit easily through cannulas

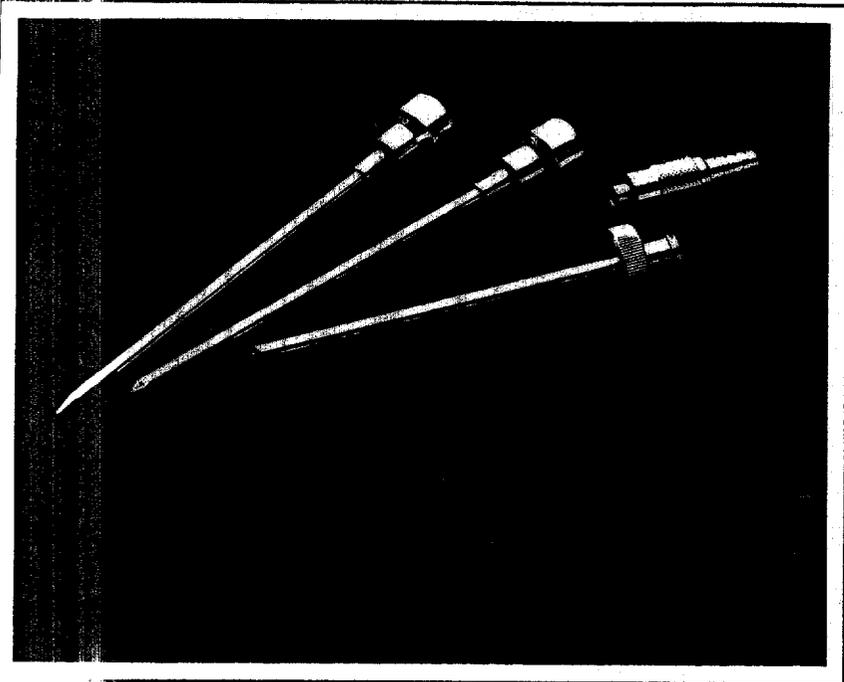


Shoulder Cannulas

Shoulder Inflow Cannula Set prevents fluid extravasation.

Eliminate the complication of fluid extravasation during shoulder arthroscopy with Instrument Maker's Shoulder Cannula Set. The 4.0mm cannula's only opening is its distal tip; side holes have been removed. A handy inflow adaptor which accepts tubing on one end is also easily screwed on and off the cannula during the procedure.

■
Item #10771
Shoulder Cannula Set
(includes Cannula, Sharp and Blunt Trocars, Inflow Adaptor), \$230.



Golden Retriever

Breaking a blade tip or part of a jaw in the joint is a situation easily resolved with the Golden Retriever. Combining the pull of a 1 1/4" magnet and suction allows you to quickly remove metal pieces from the joint. After placing suction tubing on one end, slip the Golden Retriever through your cannula, attract the metal fragment, then remove it from the joint

using the cannula walls for protection.

Be confident you've got the means to solve the broken fragment problem on the spot—get the Golden Retriever (we hope you'll never have to use it).

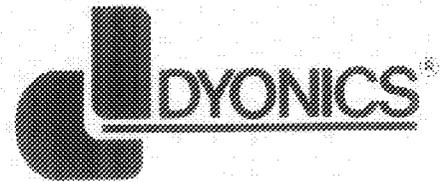
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Item #10100
Golden Retriever, \$250.



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DyoVac[®]

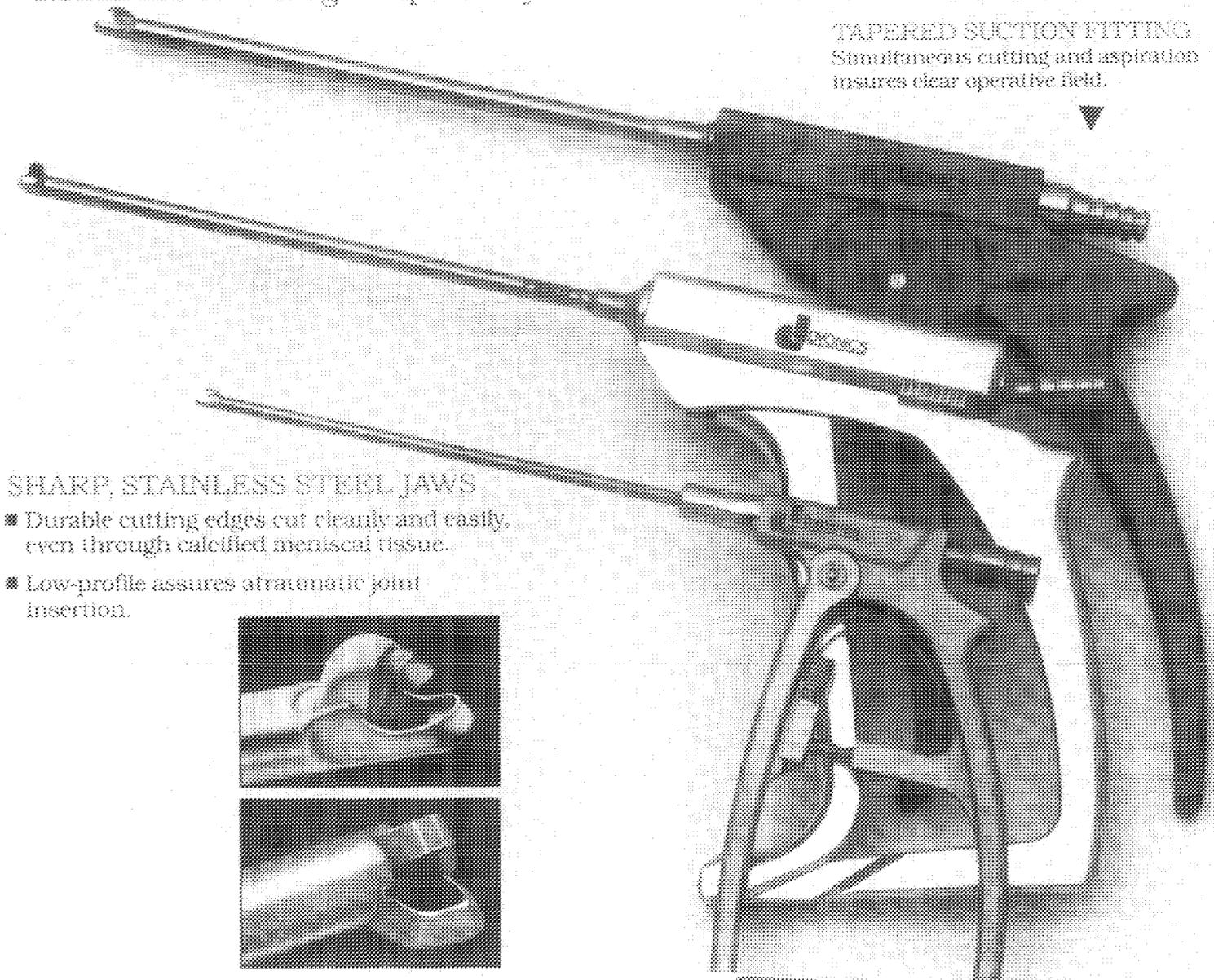
Suction Punch



Combines the convenience of a reliable and efficient manual cutting instrument with the advantage of simultaneous tissue aspiration.

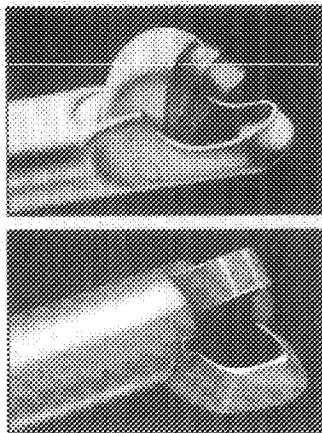
- Effective for meniscal tissue and synovial plicae resection, articular cartilage debridement, and morselizing of loose bodies.
- Unique jaw design facilitates rapid contouring of the meniscal edge.
- 90° Angled and Straight styles provide complete cutting capabilities.
- Convenient blade latch keeps jaws closed for safe introduction and removal from the joint.
- 2.5mm has been designed specifically for use in the Wrist and TM Joint

TAPERED SUCTION FITTING.
Simultaneous cutting and aspiration
insures clear operative field.

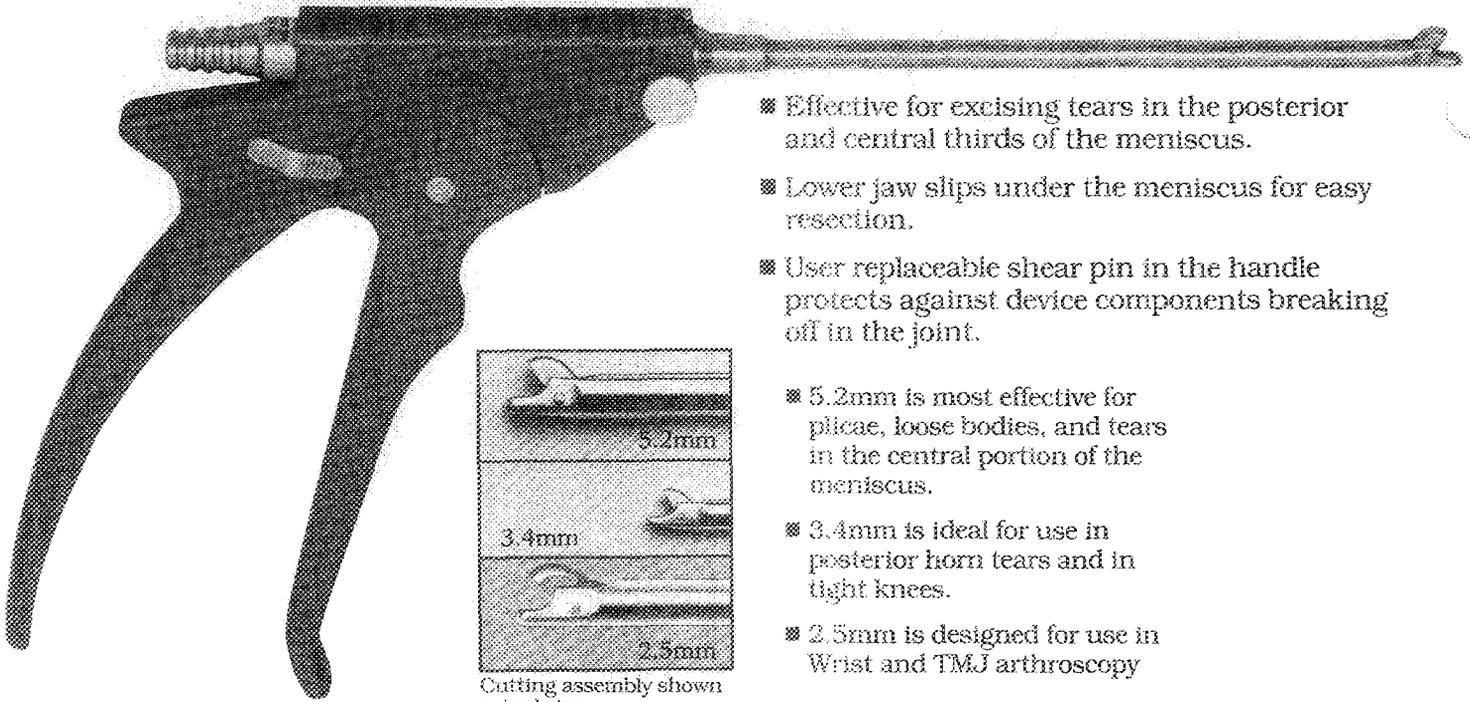


SHARP, STAINLESS STEEL JAWS

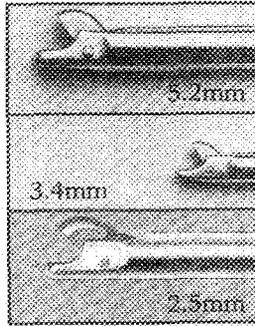
- Durable cutting edges cut cleanly and easily, even through calcified meniscal tissue.
- Low-profile assures atraumatic joint insertion.



STRAIGHT SUCTION PUNCH



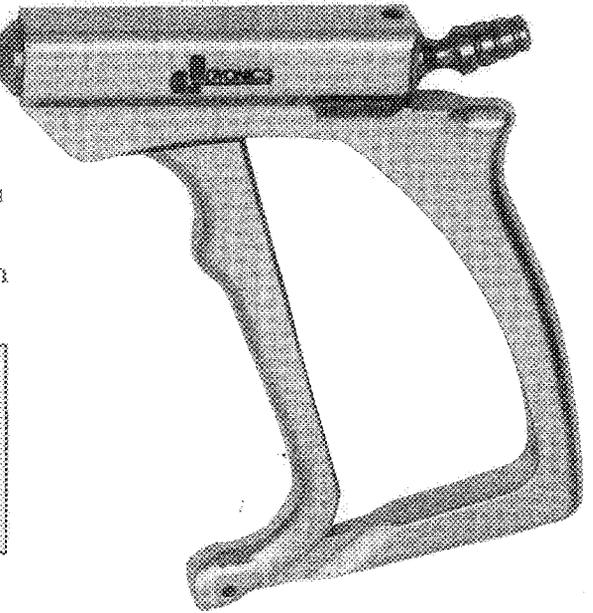
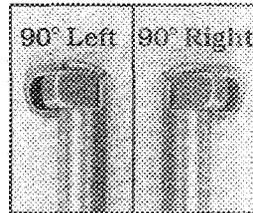
- Effective for excising tears in the posterior and central thirds of the meniscus.
- Lower jaw slips under the meniscus for easy resection.
- User replaceable shear pin in the handle protects against device components breaking off in the joint.
- 5.2mm is most effective for plicae, loose bodies, and tears in the central portion of the meniscus.
- 3.4mm is ideal for use in posterior horn tears and in tight knees.
- 2.5mm is designed for use in Wrist and TMJ arthroscopy



Cutting assembly shown actual size.

90° ANGLED SUCTION PUNCH

- Facilitates resection of tears in the anterior and central thirds of the meniscus.
- Exclusive closed-loop handle provides smooth cutting action and improves tactile feedback.
- Available in 90° Left and 90° Right angles to access lesions in both medial and lateral meniscal compartments.



ORDERING INFORMATION

Product Description	Part Number
Complete DyoVac® Suction Punch System (Includes: 3.4mm and 5.2mm Straight, 90° Right and Left)	3322
4.5mm DyoVac® Suction Punch Set (Includes: 90° Right and Left)	3321
5.2mm DyoVac® Suction Punch (Straight)	2685
3.4mm DyoVac® Suction Punch (Straight)	2707
2.5mm DyoVac® Suction Punch (Straight)	3499
4.5mm DyoVac® Suction Punch, 90° Left	3196
4.5mm DyoVac® Suction Punch, 90° Right	3197
5.2mm Cleaning Brush Kit	2697
2.5mm Cleaning Brush Kit	3577
3.4mm Cleaning Brush Kit	2715
4.5mm Cleaning Brush Kit	3349
5.2mm Blade Retention Screw Kit	2699
3.4mm Blade Retention Screw Kit	2714
3.4mm Replacement Blade Assembly	3585
5.2mm Replacement Blade Assembly	3586

SERVICE

Dyonics maintains a complete service department. Toll free number: 800-343-5717.

WARRANTY

One year warranty against manufacturer's defects on all parts and labor.

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Dyonics, Inc., 160 Dascomb Road, Andover, MA 01810
 Telephone: 800-343-8386 (sales) 800-343-5717 (service) • In Massachusetts: 508-470-2800

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VIDEO ARTHROSCOPES



4.0mm x 30°
4.0mm x 70°

The 4.0mm arthroscopes join directly to a video camera, eliminating the need for an additional endoscopic coupling device.

■ Improved high resolution optics

The Dyonics® 4.0mm VideoArthroscope's precision-fabricated optical design transmits a bright, sharp image of extreme clarity and uniform illumination. The variable focus adjustment allows the surgeon to optimize image clarity.

■ Eliminates fogging during an operative procedure

The VideoArthroscope is designed to form a watertight seal to the "C" mount flange of a solid state video camera. Disinfecting the VideoArthroscope and camera together as one unit virtually eliminates lens fogging problems.

■ Maximum maneuverability

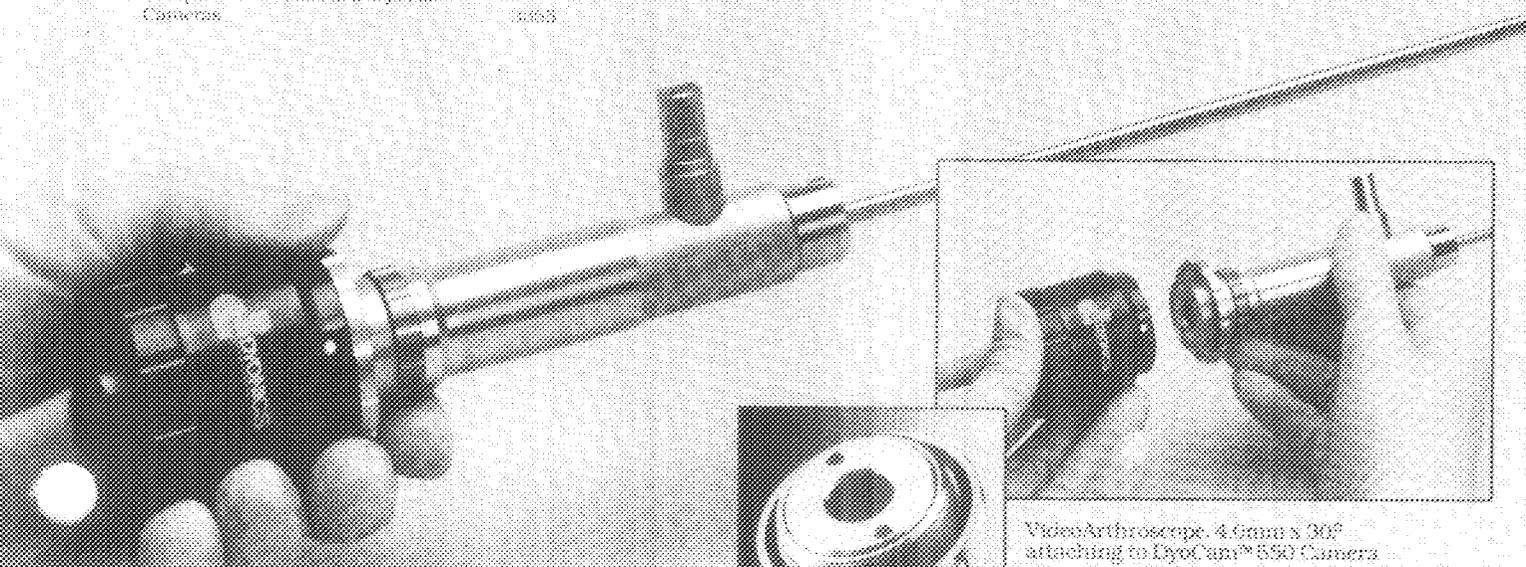
Attached to the DyoCam™ video camera, the Dyonics® VideoArthroscope provides the surgeon with a compact and lightweight video system that is unsurpassed for maneuverability and convenience.

■ Compatible with the Dyonics Cannula System

Arthroscopic surgical instruments and the VideoArthroscopes are interchangeable within the cannula system... eliminating the need for additional puncture wounds. This is especially valuable for shoulder arthroscopy, where maintaining portals may be difficult.

Ordering information

Description	Part No.	Description	Part No.	Service/Repair
4.0mm x 30° VideoArthroscope Operative System <small>(No Video Camera, Irrigation Extender, or Cannula)</small>		Operative Instrument Set, 4.0mm <small>(No. 1000) (Includes: 1. Irrigator, 2. Grasper, 3. Probe, 4. Shaver, 5. Sizer, 6. Sizer, 7. Sizer, 8. Sizer, 9. Sizer, 10. Sizer, 11. Sizer, 12. Sizer, 13. Sizer, 14. Sizer, 15. Sizer, 16. Sizer, 17. Sizer, 18. Sizer, 19. Sizer, 20. Sizer, 21. Sizer, 22. Sizer, 23. Sizer, 24. Sizer, 25. Sizer, 26. Sizer, 27. Sizer, 28. Sizer, 29. Sizer, 30. Sizer, 31. Sizer, 32. Sizer, 33. Sizer, 34. Sizer, 35. Sizer, 36. Sizer, 37. Sizer, 38. Sizer, 39. Sizer, 40. Sizer, 41. Sizer, 42. Sizer, 43. Sizer, 44. Sizer, 45. Sizer, 46. Sizer, 47. Sizer, 48. Sizer, 49. Sizer, 50. Sizer, 51. Sizer, 52. Sizer, 53. Sizer, 54. Sizer, 55. Sizer, 56. Sizer, 57. Sizer, 58. Sizer, 59. Sizer, 60. Sizer, 61. Sizer, 62. Sizer, 63. Sizer, 64. Sizer, 65. Sizer, 66. Sizer, 67. Sizer, 68. Sizer, 69. Sizer, 70. Sizer, 71. Sizer, 72. Sizer, 73. Sizer, 74. Sizer, 75. Sizer, 76. Sizer, 77. Sizer, 78. Sizer, 79. Sizer, 80. Sizer, 81. Sizer, 82. Sizer, 83. Sizer, 84. Sizer, 85. Sizer, 86. Sizer, 87. Sizer, 88. Sizer, 89. Sizer, 90. Sizer, 91. Sizer, 92. Sizer, 93. Sizer, 94. Sizer, 95. Sizer, 96. Sizer, 97. Sizer, 98. Sizer, 99. Sizer, 100. Sizer)</small>	2701	For service, please call Dyonics Customer Service Department at 800-343-3947 or in Massachusetts call 617-470-2960 for a service/replacement number.
Compatible with DyoCam 550 Camera	3325	Irrigation Extender, 4.0mm	2705	Warranty 30-day warranty against manufacturer's errors on parts and labor. Note: Full warranty statement re-included on VideoArthroscopy Instrumentation sheet.
Compatible with all other DyoCam Cameras	3320	Cannula, 4.0mm	2704	
4.0mm x 30° VideoArthroscope		Obstructor, 4.0mm	1562	
Compatible with DyoCam 550 Camera	3327	Procar, 4.0mm	1685	
Compatible with all other DyoCam Cameras	3304	Soaking Storage Jar	3178	
4.0mm x 70° VideoArthroscope		Diagnostic Cannula Set	3150	
Compatible with DyoCam 550 Camera	3330			
Compatible with all other DyoCam Cameras	3355			



VideoArthroscope, 4.0mm x 30°
attaching to DyoCam™ 550 Camera

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 real "C" Mount

ARTHROSCOPES

4.0mm x 30°

4.0mm x 70°

Precision workmanship produces a lightweight arthroscope with exceptional image clarity and uniform illumination.

■ Enhanced Optics

Improved optical design provides an increased wide angle view and enhanced fiberoptic illumination. The resulting image is brighter and sharper than ever before. Outstanding color reproduction is consistently achieved with the advanced optical system.

■ Optimal Maneuverability

Lightweight, streamlined styling provides comfortable control of the arthroscope with increased responsiveness and reduced surgeon fatigue. All arthroscope connections are aligned with the direction of view to improve maneuverability, particularly when viewing under the patella.

■ Proven Reliability

Durable opto-mechanical design provides resistance to the flexing stresses associated with arthroscopic procedures. A resilient cover lens protects the arthroscope from minor scratches.

■ Interchangeable Cannulas

Finger-posted cannulas allow for rapid repositioning of the arthroscopes, powered surgical instrument blades, and the infusion channel. This interchangeability is especially valuable in shoulder arthroscopy where establishing and maintaining portals may be difficult.

Ordering Information

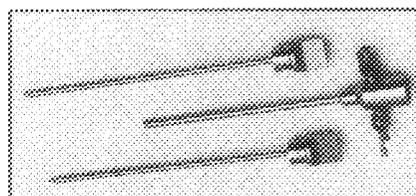
Description	Part No.
4.0mm x 30° Arthroscope Operative System <i>(Includes Arthroscope, Irrigation Extender, 4.5mm Cannula, Trocar, 4.5mm Obturator, 4.5mm Trocar, 4.5mm Cannula, 4.5mm Irrigation Adapter)</i>	2721
4.0mm x 30° Arthroscope	2713
4.0mm x 70° Arthroscope	2746
Operative Instrument Set <i>(Includes Irrigation Extender, 4.5mm Cannula, 4.5mm Trocar, 4.5mm Obturator, 4.5mm Trocar, and Irrigation Adapter)</i>	2701
Diagnostic Cannula Set	3134
Irrigation Extender, 4.5mm	2705
Cannula, 4.5mm	2704
Obturator, 4.5mm	1982
Trocar, 4.5mm	1985
Soaking/Storage Tray	3179

Service/Repair

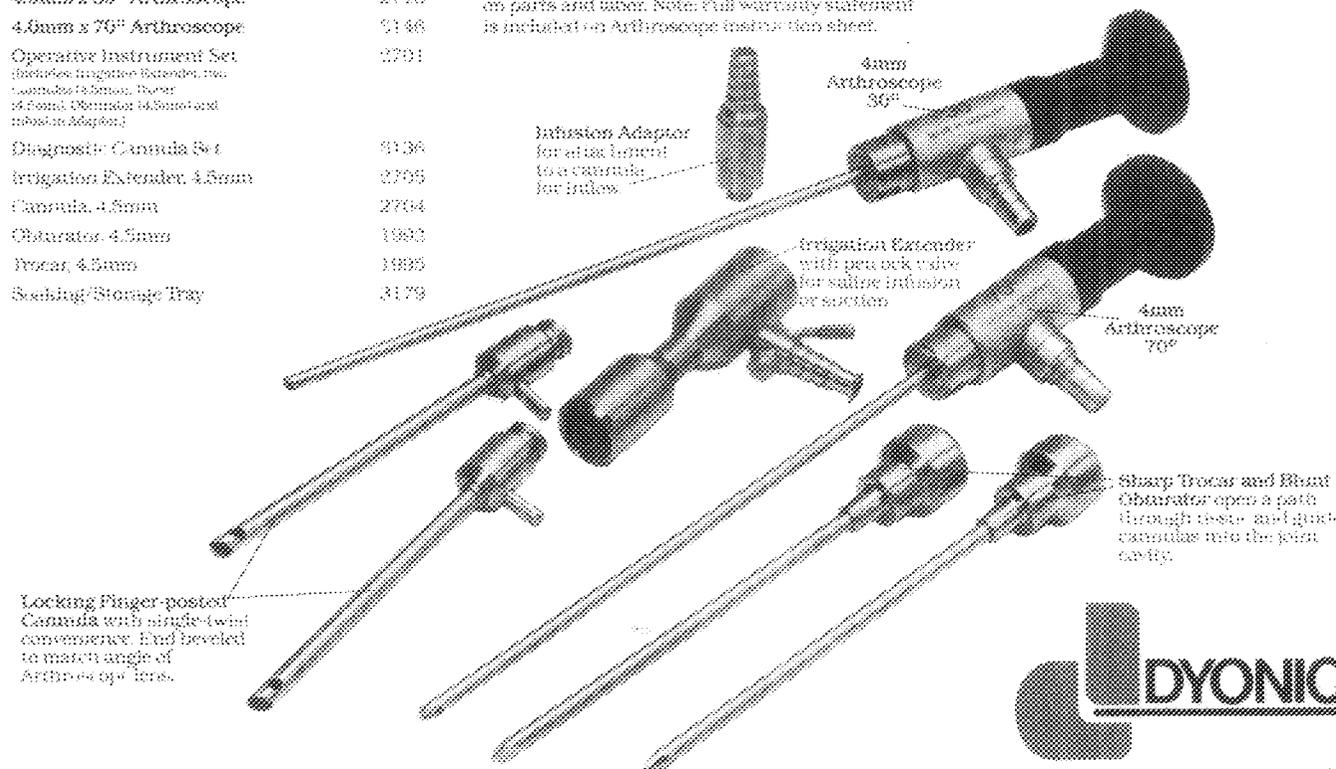
For service, please call Dyonics Customer Service Department at 800-343-5717 or in Massachusetts call 617-470-3600 for a service representative number.

Warranty

90-day warranty against manufacturer's defects on parts and labor. Note: Full warranty statement is included on Arthroscope instruction sheet.

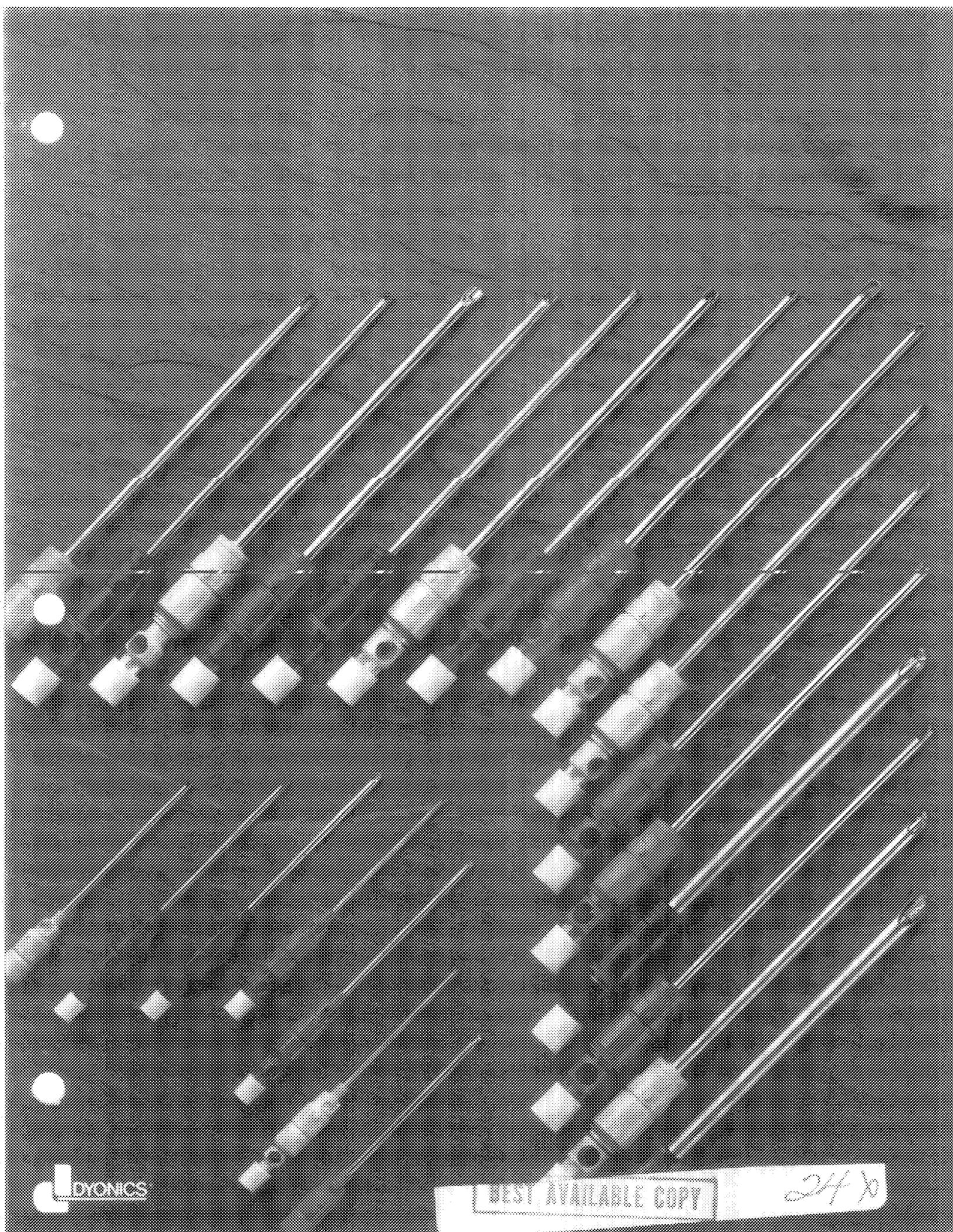


Diagnostic Cannula Set



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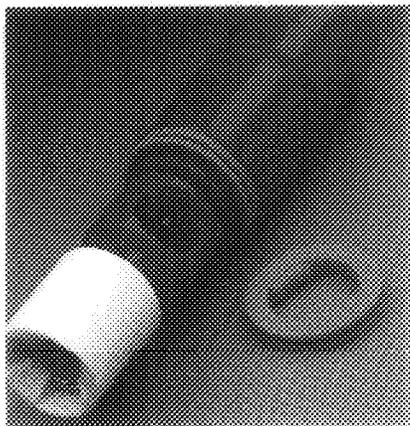


DYONICS DISPOSABLE BLADES ARE THE RIGHT TOOLS

- Better Cutting Performance
- Color Coded

It takes the "right tools" to make a procedure faster, safer, and more precise. Dyonics offers the Right Tools.

Dyonics Disposable Arthroscopic Blades give you so many advantages. They are color coded, providing easy distinctions in style and size. Many of them help the drive system "recognize" the blade style and "remember" the speed you've selected for that style. All of them provide superior "fluid dynamics," with better seals and stronger



suction at the tip... giving you better cutting performance. Plus, you have the confidence of beginning each procedure with blades you know are absolutely sharp.

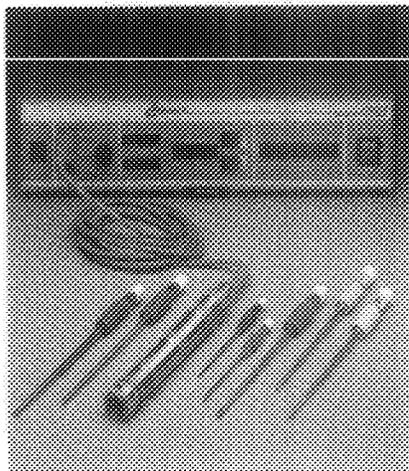
Dyonics does not merely lead the arthroscopic blade market, we virtually invented it. We've benefited from the close collaboration of surgeons who are the pioneers in arthroscopic procedures.

We introduced. The surgeons asked for more. We developed new tips and sizes.

Now, you can choose just the right tips and sizes you need for each procedure... from 16 large joint blades and 7 small joint blades. As surgeons recognize additional blade needs, Dyonics will provide them.

PS3500™ THE BLADES THAT REMEMBER

Our PS3500™ blades contain an electronic "I-D" that works with the PS3500™ Drive Unit. The Motor Drive Unit recognizes each separate



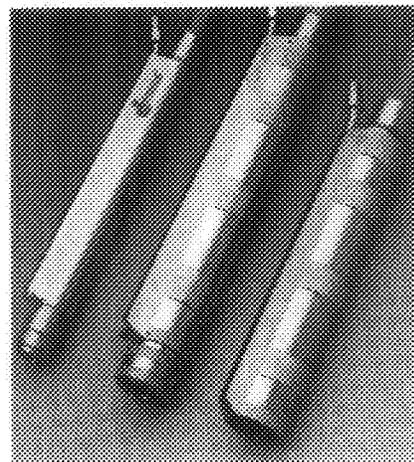
blade and its optimal speed range. You set the distinct speed you want within that range, and the Motor Drive Unit "remembers" your speed selection. The result? Faster, safer procedures, with tools that work just the way you want them to.

THE RIGHT TOOLS FOR NEW PROCEDURES

Dyonics now offers 7 Mini Blades for small joint operations. Surgeons doing wrist, ankle, elbow, and TMJ procedures can now benefit from Dyonics technology and quality.

CHOOSE FROM SUPERIOR DRIVE UNITS

Dyonics Arthroscopic Surgery Disposable Blades fit several motor



drive units. Arthroplasty and Shaver blades are compatible with Dyonics Arthroplasty and Shaver motor drive units from the Intra-Articular Surgical System, and the Universal Motor Drive Unit of the Advanced Arthroscopic Surgical System (AASS). PS3500 blades are compatible with the AASS Motor Drive Unit and the PS3500 Motor Drive Unit. Both sets fit in Dyonics canulas.

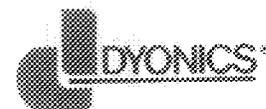
Small Joint Blades are compatible with the Mini-Motor Drive Unit and the AASS Universal Motor Drive Unit.

STERILE PACKED FOR ADDITIONAL CONVENIENCE

All Dyonics Disposable Arthroscopic Blades are packaged sterile in convenient peel-back tray and dispenser boxes. Both components of the blade assembly are sterilized separately, ensuring complete EtO sterilization.

Dyonics Disposable Arthroscopic Blades. Better cutting performance. The convenience and speed of color coding.

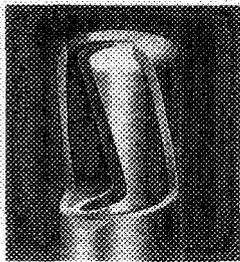
The Right Tools.



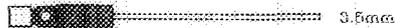
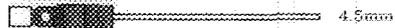
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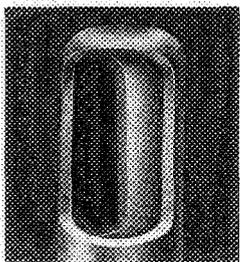
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DISPOSABLE BLADES ASSURE A SHARP EDGE EVERY TIME



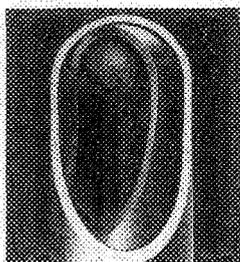
Cutter... Rounded-corner design protects articular cartilage from inadvertent damage. The open-ended blade configuration is excellent for resection of meniscal tears, plica, and selected articular cartilage lesions. The 2.9mm version works well on the triangular fibrocartilage of the wrist, and in other small joint spaces.

-  3.5mm
-  4.5mm
-  5.5mm
-  2.9mm

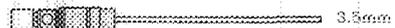
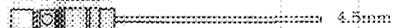


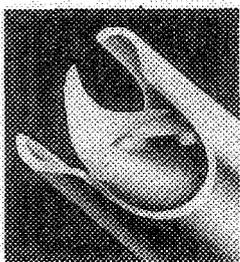
Trimmer... A closed, rounded end with a side cutting window near the tip make this a good blade for debridement in patellar chondromalacia and in the final smoothing of meniscal edges.

-  4.5mm

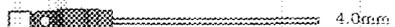


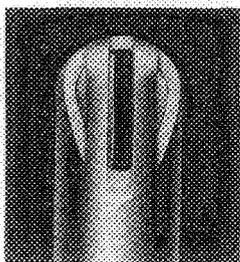
Full Radius Blade... Aggressive cutters that provide multiangle maneuverability within the joint. The bevelled-end design allows effective use as both an end and a side cutter. The smaller 2.9mm version works well in small joints, like the wrist and ankle, while the 2.0mm version handles even smaller areas like TMJ procedures.

-  3.5mm
-  4.5mm
-  5.5mm
-  2.0mm
-  2.9mm



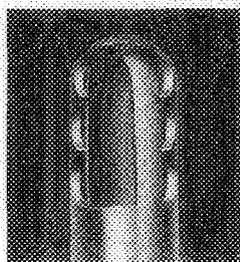
TurboCutter... An aggressive, open-ended cutter, used for the rapid removal of meniscal tissue. It is especially useful to resect flap, degenerative, and bucket handle tears in the central third and posterior portion of the meniscus.

-  4.0mm

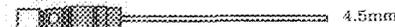


TurboWhisker... Works safely, yet aggressively, at high speeds. The 4.5mm blade works well for debridement in patellar chondromalacia or in smoothing meniscal edges and the glenoid labrum. The 2.9mm version is used in smaller joints, like the wrist and ankle, while the 2.0mm version is used in TMJ procedures.

-  4.5mm
-  2.0mm
-  2.9mm



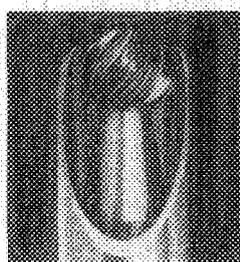
TurboTrimmer... A toothlike edge on the outer blade window allows maximum maneuverability and aggressive cutting. The rounded design aids efficient side cutting, while protecting articular cartilage from inadvertent damage.

-  4.5mm



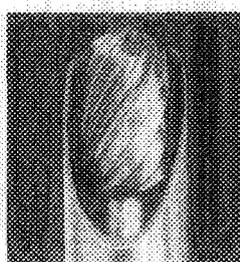
ProCutter... Designed for high speed meniscal resection. A unique distal tip configuration directs tissue into the cutting jaw to cut twice with each rotation.

-  4.0mm
-  5.0mm



Abrader... Intended for use in roughening sclerotic lesions and to remove osteophytes and attached bony "loose bodies." Large blades are designed for use in the knee, shoulder, and elbow. The 2.9mm blade is designed for use in smaller joints, like the wrist and ankle.

-  4.0mm
-  5.5mm
-  2.9mm



Acromionizer... Specifically designed to speed up and aid arthroscopic acromionectomy. The elongated burr provides better access, to smoothly resect and contour a slope under the anterior third of the scapular acromion.

-  4.0mm
-  5.5mm

Barrel Abrader... This 2.9mm blade is very useful in small joint spaces like the wrist and ankle.

-  2.9mm

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DISPOSABLE ARTHROSCOPIC SURGERY BLADES

ORDERING INFORMATION

ARTHROSCOPIC SURGERY BLADES

AASS Cat. No.	PS3500™ Cat. No.	Product Description	Size	Color
3399	3450	Abrader Blade	4.0mm	Aqua
	3451	Abrader Blade	5.5mm	Black
3401	3452	Acromionizer Blade	4.0mm	Mauve
	3453	Acromionizer Blade	5.5mm	Brown
3054	3439	Cutter*	3.5mm	Red
2963	3440	Cutter*	4.5mm	Blue
	3598	Cutter*	5.5mm	Lt Pink
3058	3442	Full Radius Blade	3.5mm	Beige
3062	3443	Full Radius Blade	4.5mm	Yellow
3059	3444	Full Radius Blade	5.5mm	Orange
3324	3447	ProCutter™ Blade**	4.0mm	Purple
3325	3448	ProCutter™ Blade**	5.0mm	Pink
2964	3441	Trimmer	4.5mm	Green
3382	3449	TurboCutter™ Blade	4.0mm	Turquoise
3528	3529	TurboTrimmer™ Blade	4.5mm	Powder Blue
3061	3446	TurboWhisker™ Blade	4.5mm	Navy Blue

MINI BLADES

Cat. No.	Product Description	Size	Color
3530	Mini Abrader Blade	2.9mm	Orange
3553	Mini Barrel Abrader Blade	2.9mm	Purple
3606	Mini Cutter*	2.9mm	Beige
3410	Mini Full Radius Blade	2.0mm	Blue
3419	Mini Full Radius Blade	2.9mm	Red
3407	Mini TurboWhisker™ Blade	2.0mm	Yellow
3418	Mini TurboWhisker™ Blade	2.9mm	Green

*Cutter-Patent No. 4,274,414

**ProCutter™ Blade. Patent Pending.

WARRANTY

Dyonics' products are guaranteed to be free from defects in material and workmanship.

STERILIZATION

Product is ethylene oxide sterilized and is provided in sterile packaging. These blades are intended for single use only and should not be resterilized.



Dyonics, Inc., 160 Dascomb Road
Andover, Massachusetts USA 01810

Call TOLL FREE 1-800-343-5717
(In Massachusetts 508-470-2800)

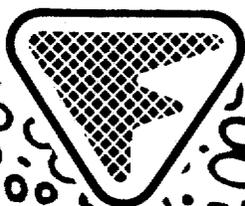
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molded
filters
for
precise
particle
control

FILTERTEK, INC.



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28

choice of filter media

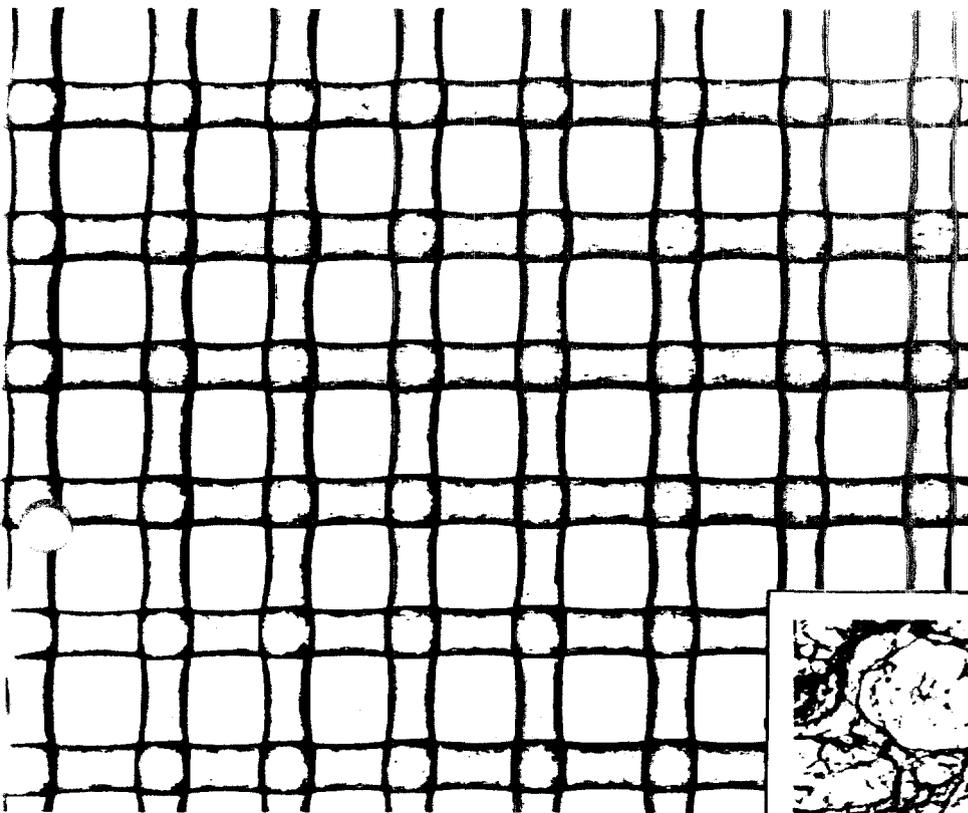
FILTERTEK utilizes a wide variety of thermoplastic materials to produce the filter media best suited for the specific application. Consideration is given to flow requirements, particle retention, self-cleaning properties, pressure drop, and, of course, economy.

In most cases woven monofilament screens . . . having either a square or dutch twill weave . . . perform maximally. For even more precise filtration requirements, special non-woven media is recommended.

Five popular types of media are illustrated on the following pages for comparative purposes.

Woven Monofilament Screen

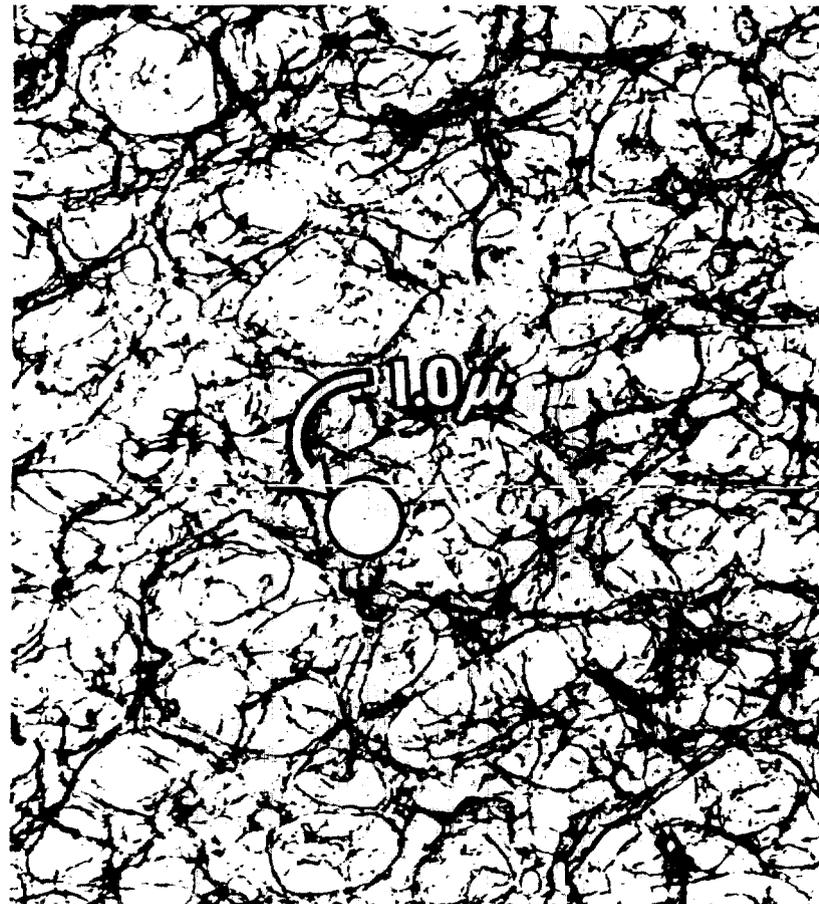
Rugged monofilament provides a very serviceable filter media for many applications. The example illustrated is a square weave. This media is available in nylon, polyester, polypropylene, and teflon, with mesh openings of 10 microns (.000394") and larger. The smooth thread surface provides excellent self-cleaning action and flow characteristics up to 20% better than wire cloth equivalents. The selection of this material assures complete resistance to fatiguing due to aging, vibration, or flexing.



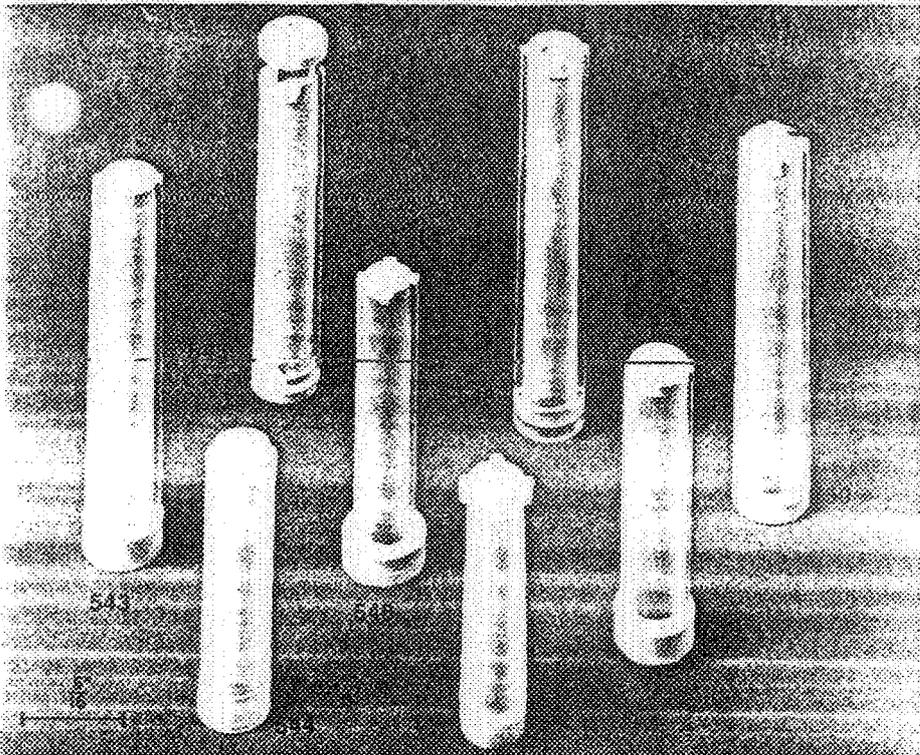
ENLARGED 100X

Reinforced Membrane Filter Media

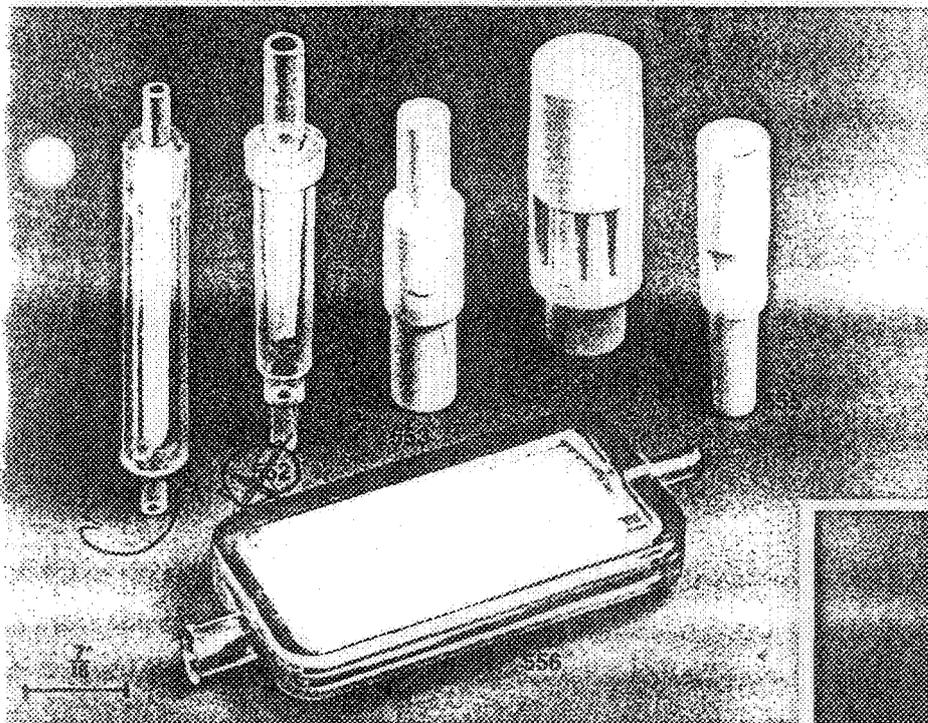
This microporous film made of biologically safe materials is reinforced with nylon for exceptional toughness. A choice of six different pore sizes, ranging from 0.2 micron to 5 microns in size, occupies 75% of filter volume. Absolute pore sizes make this media excellent for filtering out microorganisms and providing filtrates free of submicron particulate matter. Basically hydrophilic, this media, when wet, will allow passage of aqueous solutions, but prevent the passage of gases. Selected grades are available in special sizes with water repellent (hydrophobic) characteristics which will permit passage of gases, but will retain aqueous solutions. The combination of the two grades, hydrophobic and hydrophilic, permits the design of specialized self-venting filter assemblies. Acropor®



ENLARGED 40,000X



No.	Description
543	265 μ Polyester Screen and ABS Frame Blood Filter.
544	265 μ Polyester Screen with Polypropylene Frame Blood Filter.
545	170 μ Nylon Screen and ABS Frame Blood Filter.
546	265 μ Polyester Screen and Polypropylene Frame Blood Filter.
547	210 μ Nylon Screen and ABS Frame Bubble Filter.
548	150 μ Polyester Screen and ABS Frame Blood Filter.
549	100 μ Nylon Screen and ABS Frame Blood Filter.
550	265 μ Polyester Screen and ABS Frame Blood Filter.

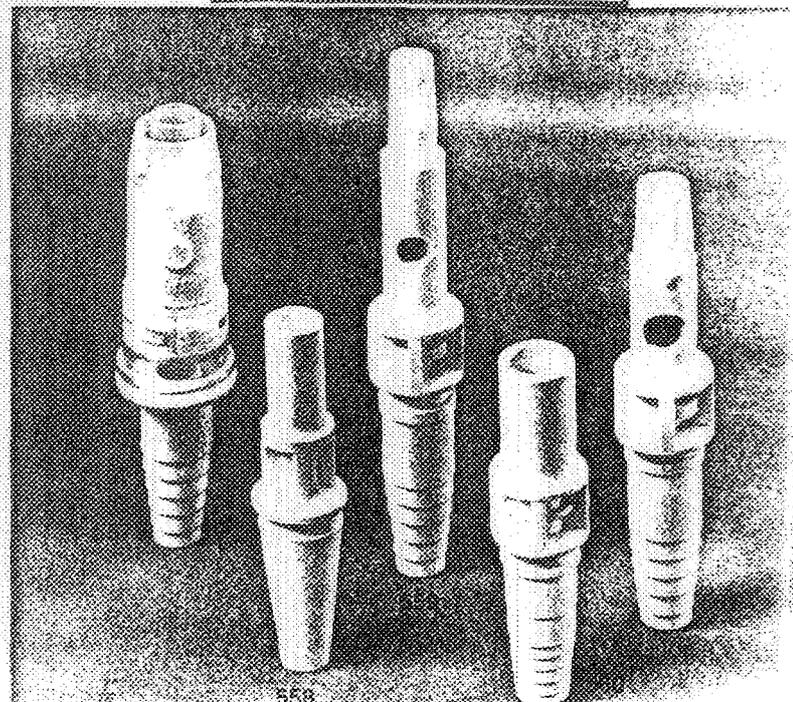


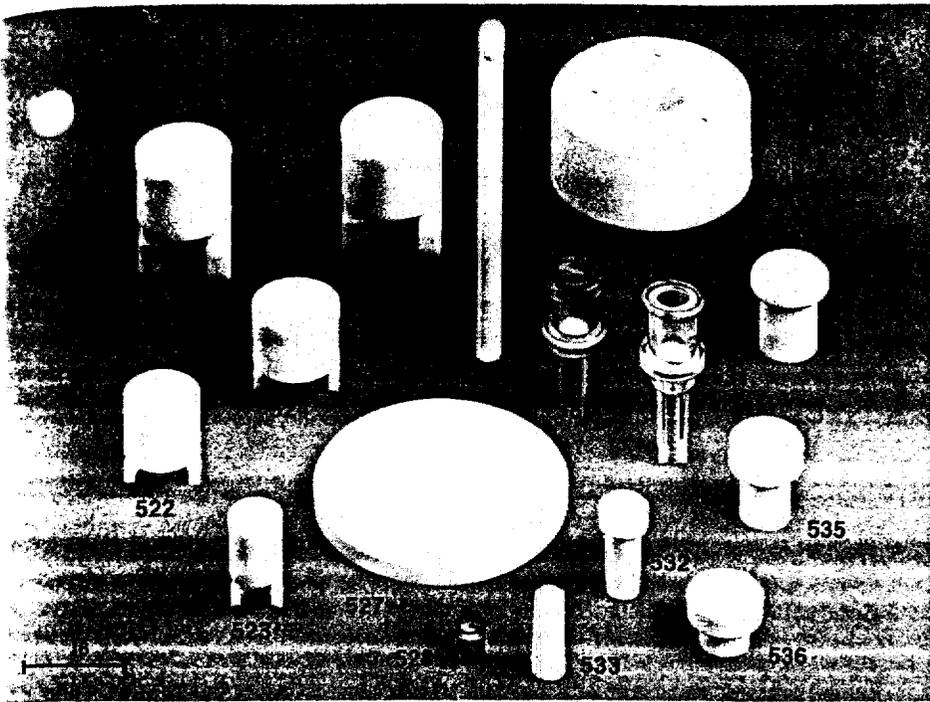
551	5 μ Reinforced Hydrophilic Membrane Media and Acrylic Frame Particulate Filter.
552	5 μ Reinforced Hydrophilic Membrane Media and Acrylic Frame Inline Particulate Filter.
553	ABS Frame with Elastomer Band Sampling Port.
554	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Line Vent Filter.
555	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Vented Filter Adapter.
556	.32 μ Hydrophilic Membrane Media and Acrylic Frame Inline Filter.

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No.	Description
557	.45 μ Reinforced Hydrophobic Membrane Media and Acrylic Frame with Elastomer Sample Port, Vented Catheter Connector and Anti-Reflex Valve Assembly.
558	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Vented Catheter Adapter.
559	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Vented Catheter Connector with Sampling Port.
560	.45 μ Reinforced Hydrophobic Membrane Media with ABS Frame Vented Connector.
561	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Vented Connector.

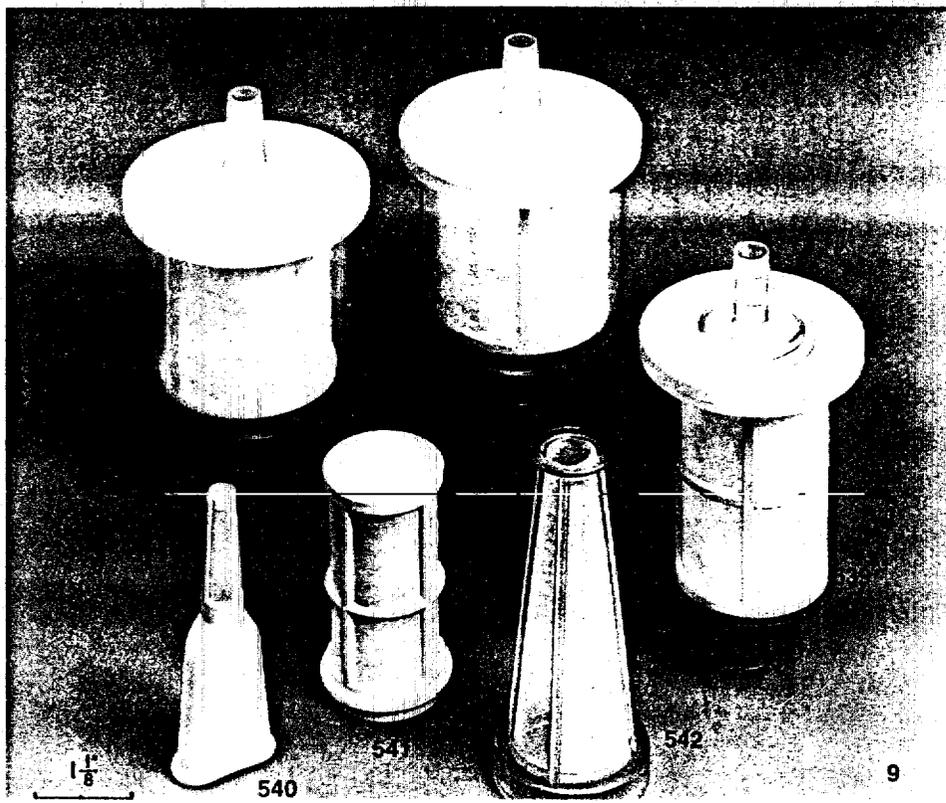




No.	Description
521	5 μ Nylon Screen and Nylon Frame Filter Tip, 1/2" dia.
522	5 μ Nylon Screen and Nylon Frame Filter Tip, 7/16" dia.
523	5 μ Nylon Screen and Nylon Frame Filter Tip, 9/16" dia.
524	5 μ Nylon Screen and Nylon Frame Filter Tip, 3/8" dia.
525	5 μ Nylon Screen and Nylon Frame Filter Tip, 5/8" dia.
526	74 μ Polyester Screen and Polypropylene Frame Cell Counter Filter.
527	8 μ Reinforced Hydrophobic Membrane Media and ABS Frame Medical Administration Filter.
528	74 μ Polyester Screen and Acrylic Frame Inline Medical Administration Filter.
529	5 μ Reinforced Hydrophobic Membrane Media and ABS Frame Drip Chamber Vent.
530	6 μ Polyester Screen and Acrylic Frame Inport Filter.
531	5 μ Reinforced Hydrophobic Membrane Media and Polycarbonate Frame Needle Hub.
532	.45 μ Reinforced Hydrophobic Membrane Media and Polyethylene Frame Vent Plug and Filter.
533	10 μ Nylon Screen and Nylon Frame Inline Filter Element.
534	.45 μ Reinforced Hydrophobic Membrane Media and Polyethylene Frame Vent Filter Cap.
535	8 μ Reinforced Hydrophobic Membrane Media and Acrylic Frame Filter Cap.
536	8 μ Reinforced Hydrophobic Membrane Media and ABS Frame Vent Cap.

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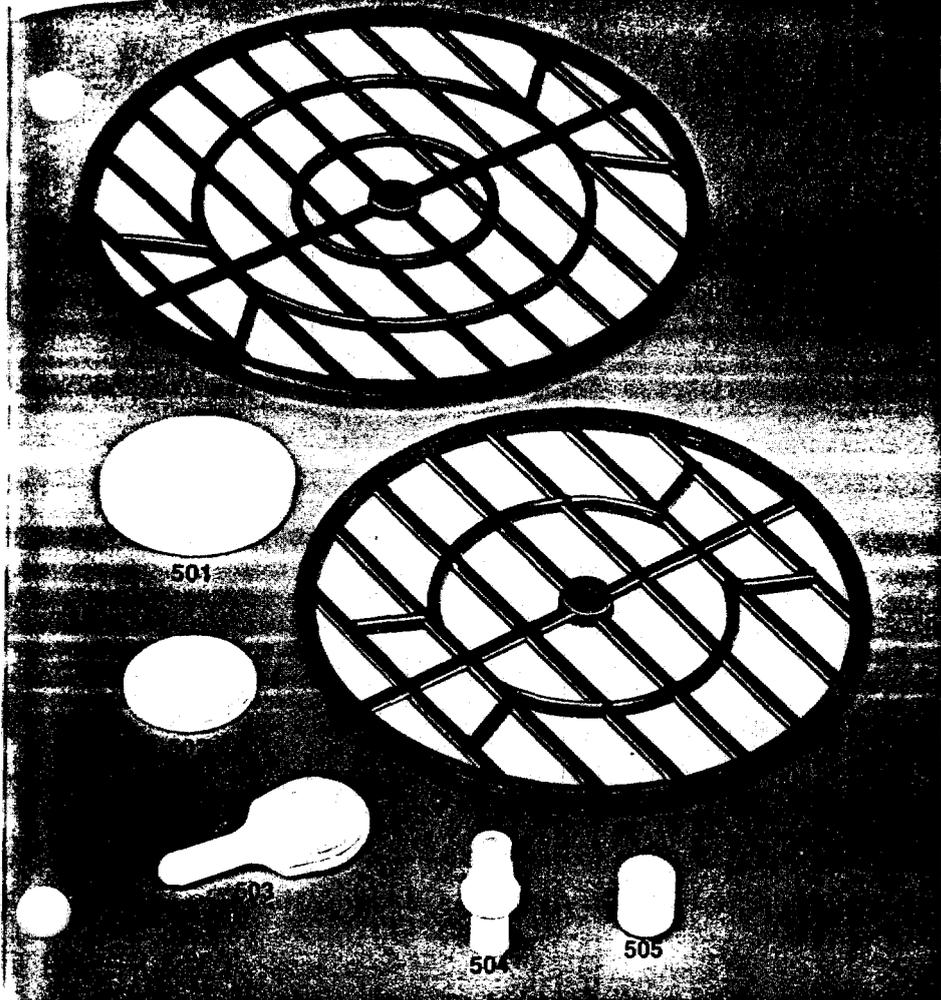
No.	Description
537	5 μ Reinforced Hydrophilic Membrane Media and Propionate Frame Pre-Bypass Filter.
538	5 μ Reinforced Hydrophilic Membrane Media and Propionate Frame Pre-Bypass Filter.
539	5 μ Reinforced Hydrophilic Membrane Media and Acrylic Frame Pre-Bypass Filter.
540	48 μ Nylon Screen and ABS Frame Mouthpiece with Filter.
541	5 μ Reinforced Hydrophilic Membrane Media and ABS Frame Pre-Bypass Filter Element.
542	265 μ Polyester Screen and Propionate Frame Large Particulate Medical Filter Cone.



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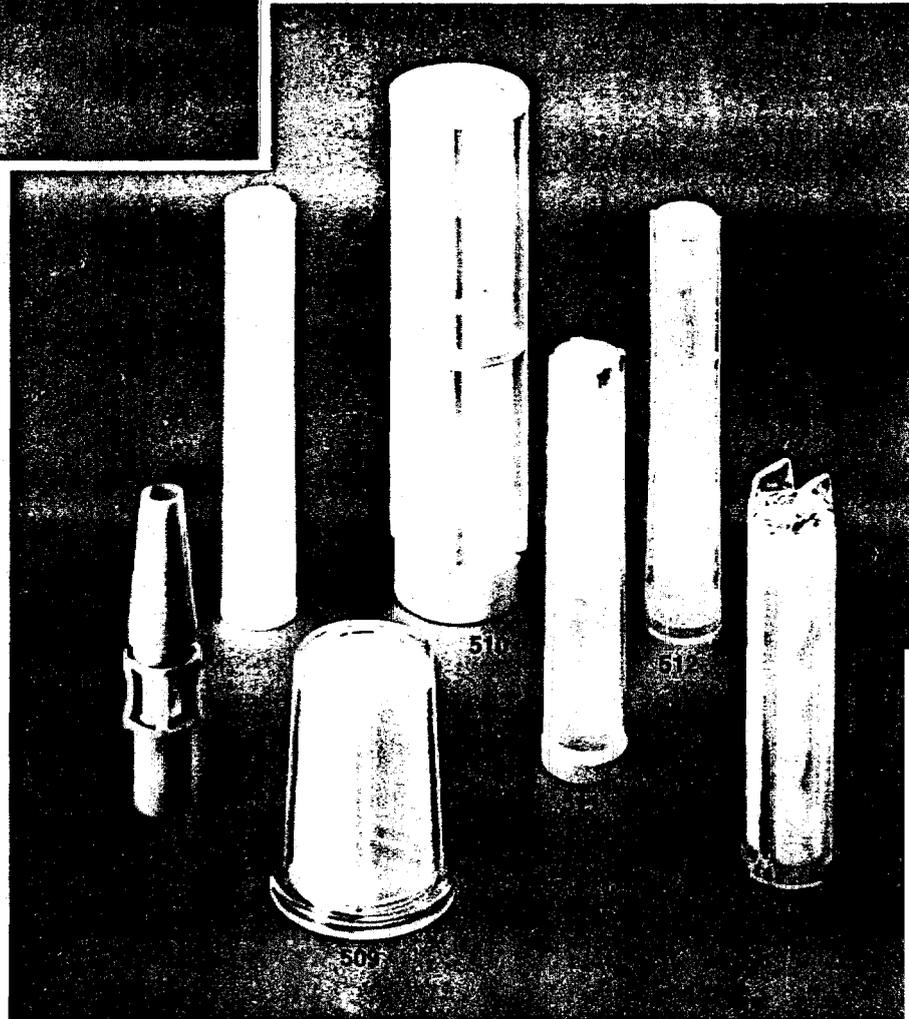
health care filters

The biologically sterile standards of the health care industry are satisfied by a wide variety of FILTERTEK filters.

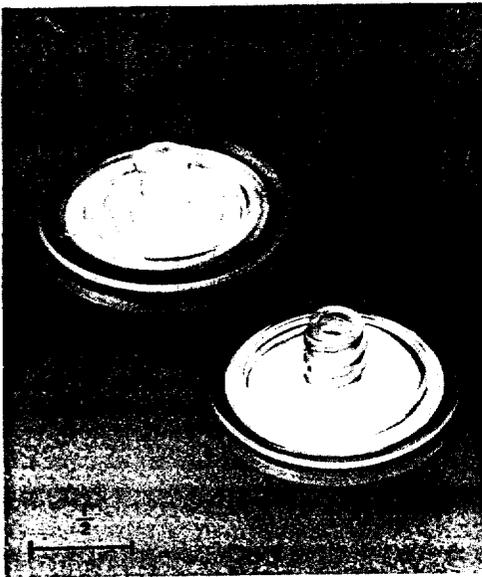


No.	Description
500	170 μ Polyester Screen and Polycarbonate Frame Blood Filter
501	.8 μ Reinforced Membrane Media and ABS Frame Medical Administration Filter
502	10 μ Nylon Screen and Nylon Frame Diagnostic Test Instrument Filter
503	149 μ Polypropylene Screen and Nylon Frame Test Instrument Filter
504	100 μ Teflon Screen and Polypropylene Body Inline Medical Filter
505	.45 μ Reinforced Hydrophobic Membrane Media and Polypropylene Frame Air Venting Filter
506	170 μ Polyester Screen and Polycarbonate Frame Blood Filter

No.	Description
507	263 μ Nylon Screen and ABS Frame Blood Administration Filter
508	.45 μ Reinforced Hydrophobic Membrane Media and ABS Frame Inline Air Venting Filter
509	265 μ Polyester Screen and Polycarbonate Frame Blood Filter
510	120 μ Nylon Screen and ABS Frame Blood Filter
511	263 μ Nylon Screen and ABS Blood Filter Frame
512	263 μ Nylon Screen and Polypropylene Frame Blood Filter
513	170 μ Nylon Screen and Propionate Frame Blood Filter

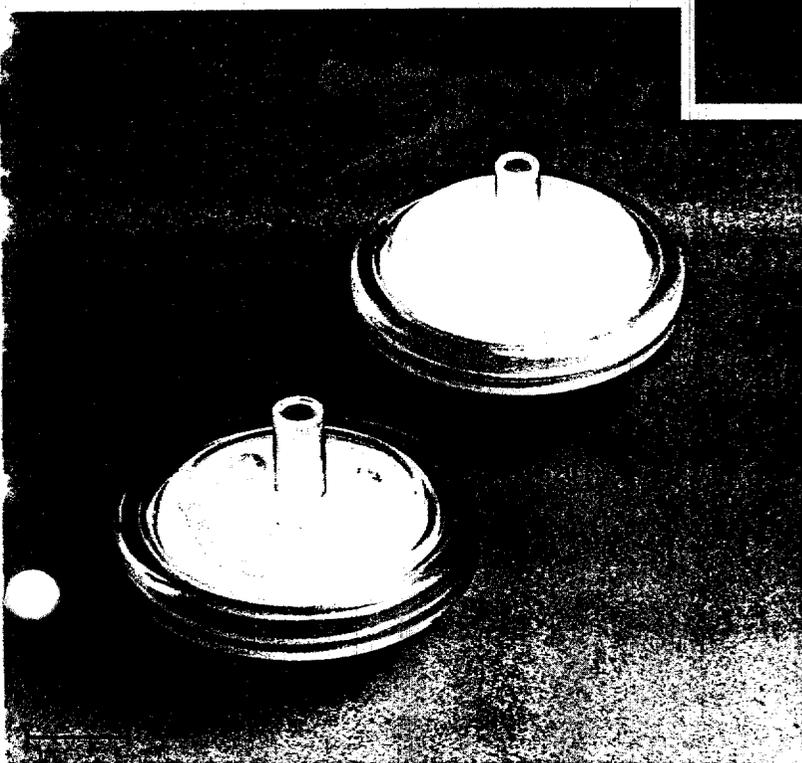
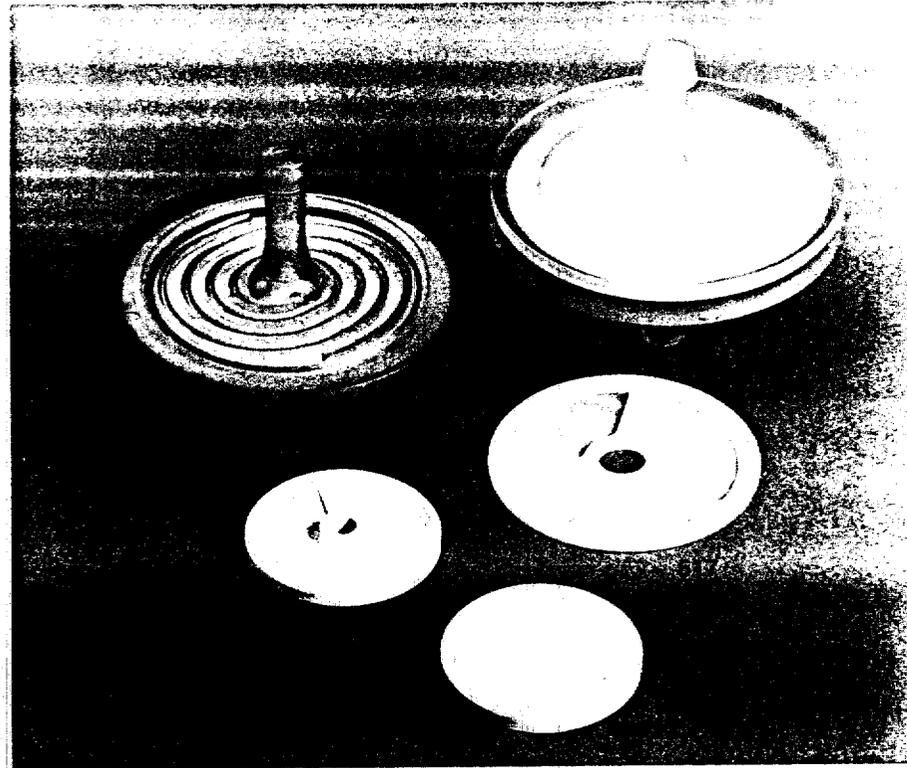


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No.	Description
514	1 μ Glass Fiber Filter Media and Acrylic Frame Drive Line Filter
515	1 μ Glass Fiber Filter Media and Acrylic Frame Gas Filter
516	.8 μ Reinforced Hydrophilic Membrane Media and ABS Frame Medical Administration Filter
517	48 μ Nylon Screen and Nylon Frame Filter Disc
518	.8 μ Reinforced Hydrophobic Membrane Media and ABS Frame Medical Administration Filter

No.	Description
519	25MM Inline Filter available with tab or threaded female luer lock inlet and male luer slip outlet. This filter is available with either hydrophobic or hydrophilic membrane filter media in retention ratings from 0.2 to 5.0 microns. The modified acrylic multipolymer housing incorporates a patented membrane sealing method which gives pressure resistance and large effective flow area.

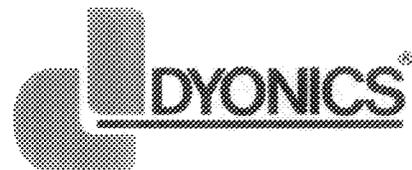


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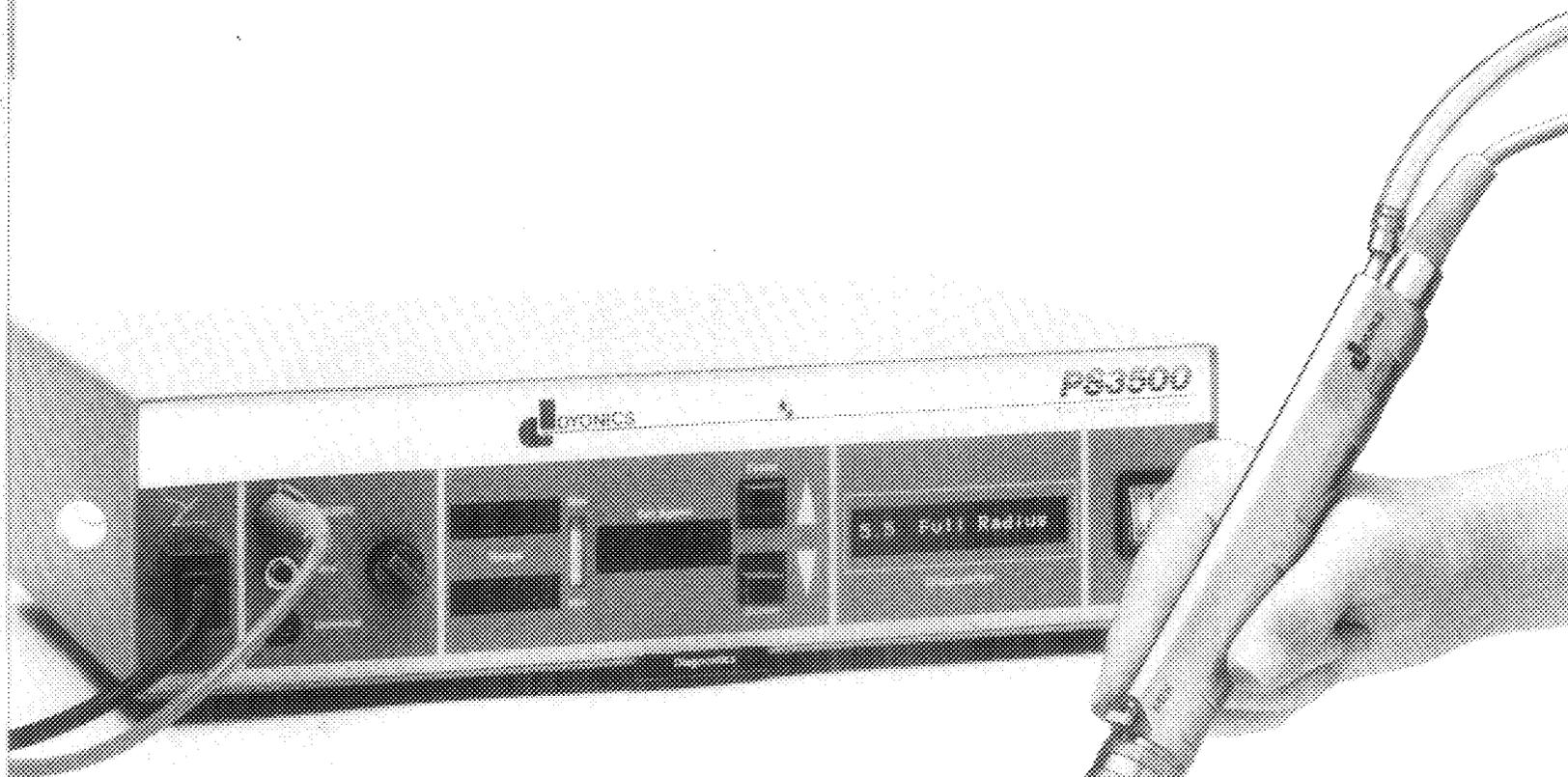
No.	Description
520	37MM Inline Filter with female luer inlet and male luer slip outlet is available both with and without 0.02 micron teflon hydrophobic air vents on the inlet side of the housing. The patented membrane sealing method assures the ability to bubble point the 0.22 micron hydrophilic filter media, which is standard in this assembly. The modified acrylic multipolymer housing can be readily solvent bonded to tubing or plastic fittings as required.

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PS3500™



ARTHROSCOPIC SURGICAL SYSTEM Manual



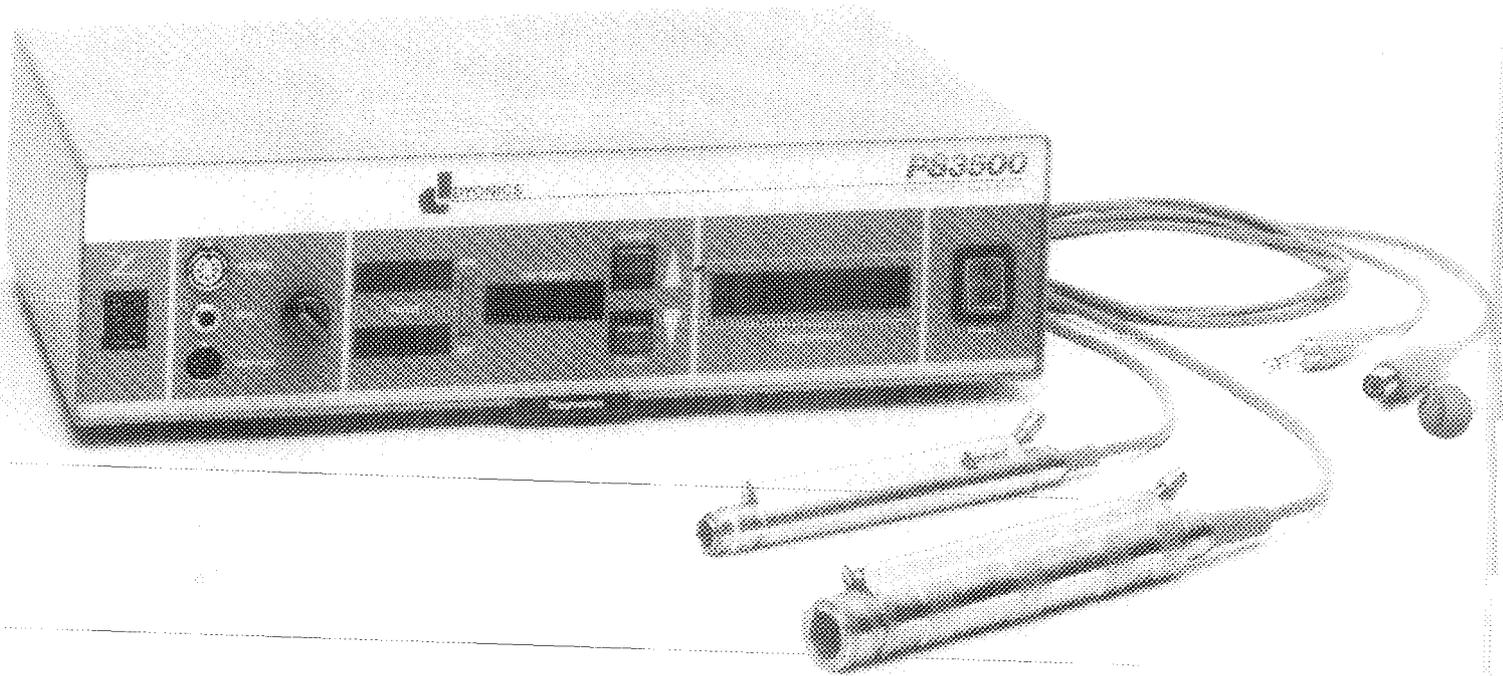
General Operating Instructions

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PS3500TM Arthroscopic Surgical System

Your Dyonics PS3500 Arthroscopic Surgical System* is a multi-function system. You can select the operating characteristics in your PS3500 high speed Motor Drive unit that meet your patient's surgical needs for abrasion arthroplasty, synovectomy, or intra-articular cutting and shaving. An optional Mini Motor Drive unit is available that will broaden your application for arthroscopic surgery. Preselected optimum blade speed operating ranges have been established for the system. Within each range you may select and change at any time the speed that is best for your technique. The system will automatically return to the last speed established for each blade upon reinsertion of a particular blade style during the same or subsequent operations.

Please read this manual carefully before you use the PS3500 System. You will learn what this product will do and how to take care of it. The maintenance procedures take little time and effort, and will ensure optimum performance. They will ensure many hours of reliable operation.



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PS3500™ Arthroscopic Surgical System

Indications

Under arthroscopic direction, the PS3500 System is intended to resect damaged tissue and remove extraneous matter found in articular body cavities. The system may be used to repair tears and other defects, remove loose fragments, shave away debris, and perform appropriate synovectomy procedures.

The PS3500 System has been designed with preselected speed range and torque for each blade style.

Clinical indications for abrasion arthroplasty include degenerative arthritis with a complaint of pain, especially at night or while standing or walking. Pathological confirmation includes exposed bone. Clinical indications for synovectomy include synovitis resulting from torn meniscus.

Use an abradar to debride exposed sclerotic lesions on the tibial, femoral, or patellofemoral surface.

Use a synovial resector to remove reactive synovitis and to smooth rough areas of articular cartilage.

Contraindications

The PS3500 Arthroscopic Surgical System should not be used with patients exhibiting ankylosis without adequate joint space or distention for arthroscopic inspection.

Abrasion arthroplasty may not be effective in treating heavy patients or those with ankylosis, instability, or expectations beyond the relief of pain. Varus or valgus deformity is not of itself a contraindication in patients with good range of motion and without gross instability or extreme

malalignment (15 deg. varus, 30 deg. valgus). Intracortical abrasion arthroplasty may be contraindicated in patients not qualifying for high tibial osteotomy or total knee replacement.

Synovectomy is contraindicated where the disease has progressed beyond the phase of synovial proliferation, and in advanced rheumatoid arthritis where erosion of the articular cartilage is present.

Precautions

Before using the PS3500 System for the first time, you should review critically all available information. The list of references on the back cover will be helpful.

A complete and comprehensive preoperative medical history and physical examination are suggested. X-ray evaluation and laboratory investigation may be included.

Before attempting abrasion arthroplasty, you should be able to perform a comprehensive arthroscopic examination. You should also be experienced in arthroscopic surgery with powered instruments such as the Advanced Arthroscopic Surgical System with the Shaver or Arthroplasty AutoSensor, the Dyonics Arthroscopic Surgery System, or the Dyonics Intra-Articular Surgical System II.

Healthy intra-articular soft tissue and cartilage can be injured by the blades and abradars. Use every available means to avoid such injury. The vascularity of subchondral bone extends into the cortical layer. Abrasion should therefore extend no deeper than 1-2mm into the cortex and not into cancellous bone.

CAUTION:

Direct contact of the rotating cutting edge of blades or burrs with metal (e.g., cannula, arthroscope, or other instrument) can cause damage to the instrument tip. This damage can range from slight distortion and/or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact should inadvertently occur, it is important to stop using the blade immediately and examine the instrument tip carefully for evidence of cracks or fractures. If there is any doubt about the condition of the blade assembly, the blade should be discarded and replaced with a new one, or in the case of reusable blades, returned to Dyonics for evaluation.

Suggested Technique

Arthroscopic surgery of the knee requires adequate joint distention to permit a clear view. Suspend 6 liters of saline 1-2 meters above the patient. Use the Dyonics 5.5mm inflow cannula for entry into the supra-patellar pouch; gravity inflow through a Verres needle or arthroscope may not provide adequate distention.

Effective cutting requires outflow with 14-16 inches (35.6-40.6cm) of mercury in-line continuous suction pressure.

The distention and suction required when using the Mini Motor Drive unit vary with the joint.

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Post Operative

After abrasion arthroplasty, a two month period of non-weightbearing ambulation is mandatory. This allows proper avascular articular surface repair, and should be accompanied by active range of motion exercises three times a day. During the two months, the patient should avoid extremity loading, weightbearing, or range of motion activity with stress. The reparative articular cartilage must mature for at least six months before you can determine the success of the procedure.

Specifications

CONTROL UNIT:

Size: 16.4"W x 11.2"D x 4.7"H
Weight: 17 pounds

FRONT PANEL:

Power Switch: On/Off (I/O)
Diagnostic Display: 16 character linear message display
Motor Speed Select Switches: Pair of momentary push switches
Speed Display: Array of LED's
Maximum and Minimum speed, selected (set) speed
Vertical bar graph indicating relative speed setting within available range
Motor Select Switch: PS3500™, Mini, and Universal Drive Unit
Motor Drive Unit Connectors: PS3500, Mini, and Universal Drive Unit
Footswitch Connector

REAR PANEL:

Cooling: Exhaust fan
AC Power: Detachable cord with a three prong hospital grade connector
Access ports: Removable panel provides access to the expansion port (left). A 25 pin connector is provided for the RS232 port (right).

CAUTION:

Only Dyonics approved equipment should be connected to RS232C and/or expansion port connectors.

MOTOR DRIVE UNIT:

Length: 7.3"
Weight: 18 ounces
Equipped with 8-foot autoclavable, replaceable power cord.

FOOT PEDAL:

Size: 7"W x 5.5"D x 2"H
Weight: 3 pounds
Directional switches: Forward/reverse/oscillate

System Components

Your PS3500 System contains four basic elements:

1. Control Unit capable of variable speed operation of the PS3500, Universal, and Mini Motor Drive units
2. Footswitch to control the power from the Control Unit to the motor drive units
3. PS3500 Motor Drive unit capable of running between 350 rpm and 3500 rpm. A spare cord is included.
4. Thermoplastic Sterilization Tray with insert Five Blade Tray

Optional

The Mini Motor Drive unit is also available. This motor drive used in conjunction with an Accessory Kit will position you for highly efficient tissue resection and removal during operative arthroscopy procedures performed on small joints.

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Operating Instructions

Control Unit Panels

The picture (A) shows the front panel of the Control Unit. The Power Switch (a) is at the far right of the panel. When you are not using the system keep the switch in the off (O) position.

The Diagnostic Panel (b) is a 16 character display capable of relaying various operating messages, blade type, and alarm conditions.

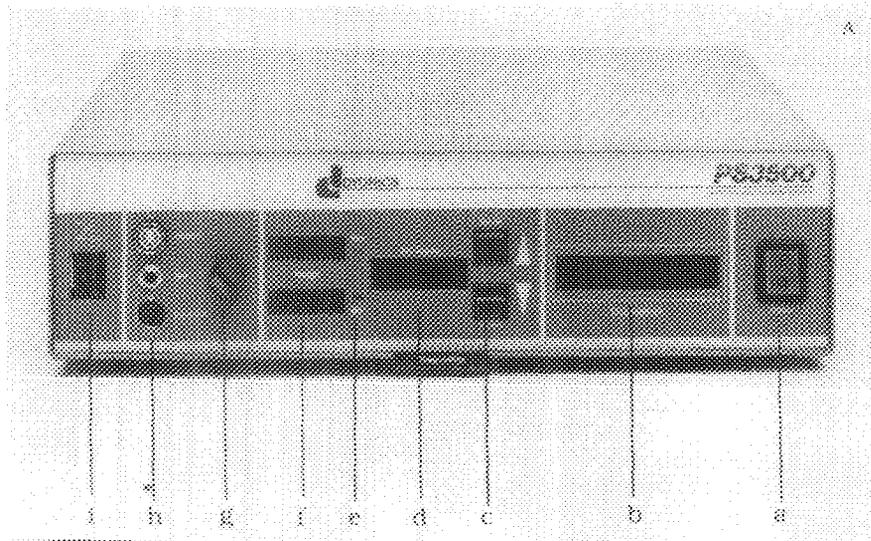
The Speed Selection switches (c) enable the operator to increase (Faster ▲) or decrease (Slower ▼) the most recently set speed for the motor drive unit within the factory preset range (f). The Speed Display (d) indicates the current speed selected within that range. Also, a Vertical Array Bar Graph (e) indicates the relative position of the selected speed within the min/max limits available.

The Control Unit features an automatic Blade Speed Recall (BSR) function. The system will automatically recall the last selected speed within the pre-determined ranges for each blade style. The operator will not be required to change speeds when blades are changed during a procedure. The PSS3500™ system will recall speeds even after the power has been turned "off" (O) and "on" (I).

The Motor Selector Switch (g) allows you to select the motor drive unit you will use: PSS3500, Mini, or Universal. The appropriate motor must be plugged into the corresponding outlet (h). The Diagnostics will detect a mismatched selection and indicate "CHECK MOTOR" when the Footswitch is depressed.

The Footpedal cord is connected to the Control Unit through the far left outlet (i). A missing or poorly connected Footswitch will be detected and indicated on the Diagnostic Display as "FOOTSWITCH".

A slide out tray labeled "Diagnostics" is located underneath the unit for your convenience in troubleshooting.



Assembling the System

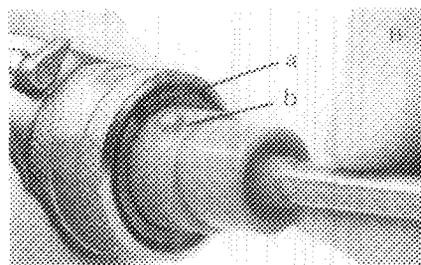
Connect the Footpedal cord to the labeled socket on the front of the Control Unit. Plug the PSS3500 Motor into the receptacle labeled PSS3500. The motor cord should be aligned with its ridge at the twelve o'clock position. The Mini and Universal Motors can also be run from the Control Unit by connecting them to the correspondingly labeled receptacle. The system has been designed so that each motor drive

unit will function only if its cord is inserted into the correct socket, and the Motor Selector Switch is in the appropriate position.

Turn the Motor Selector Switch on the Control Unit to its upper position labeled "PSS3500". If another motor drive unit is to be used, turn the Motor Selector Switch to the appropriate position. Power is supplied only to the selected motor drive unit.

Changing Blades

Blade Insertion: PSS3500 and Mini Motors



The PSS3500 and Mini Motor Drives each have a spring loaded ring at the distal end of the motor, permitting blade insertion and removal (B).

1. To insert a blade, slide the release ring on the distal end of the motor toward the proximal end as

shown. This will reveal the key slot (a) on the motor drive. Orient the motor drive so that you can see the key slot (a) and the key (b) on the blade. Insert the blade into the motor drive so that the key goes into the slot. Let the release ring slide back to its original position. Note that the cutting aperture is aligned with the ridge on the motor drive. This feature allows for tactile orientation.

2. To remove a blade, slide the release ring toward the proximal end of the motor drive unit, and simultaneously withdraw the blade.

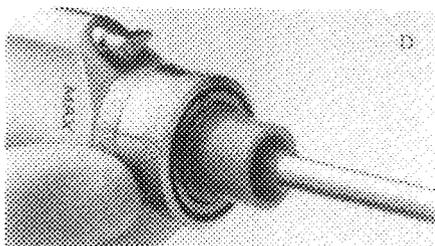
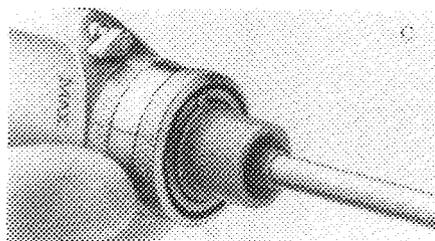
If suction is being applied you will perceive a slight force holding the components together.

Variable Suction Control

The PS3500™ and Mini Motor Drive units afford variable fingertip control of fluid outflow. The surgeon can easily select minimum suction, maximum suction, or any setting that falls between these extremes.

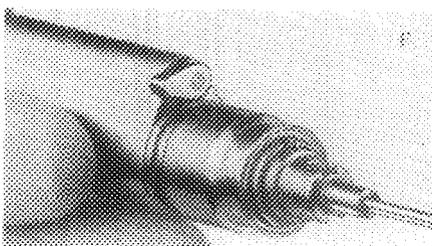
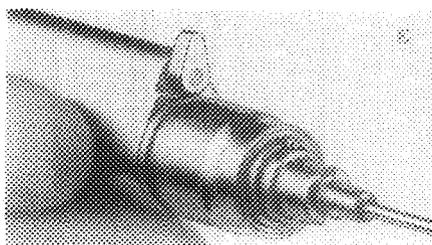
PS3500 Motor Drive Unit

1. Maximum flow is achieved by positioning the suction control lever to the left of the PS3500 Motor Drive Handpiece (C).
2. Minimum flow is achieved by positioning the suction control lever to the right of the PS3500 Motor Drive Handpiece (D).



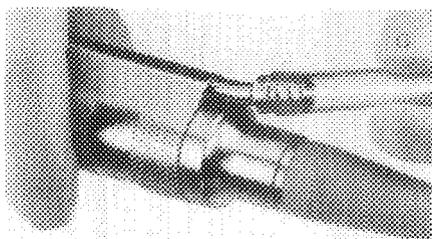
Mini Motor Drive Unit

1. Maximum flow is achieved by positioning the suction control lever perpendicular to the Mini Motor Drive Handpiece (E).
2. Minimum flow is achieved by pressing the suction control lever completely against the handpiece in either direction (F).



Connecting the Suction

Push the tab from the suction source firmly onto the suction portal which is located at the proximal end of the Motor Drive unit (G).



Inflow Cannula

After you have inserted the infusion cannula into the joint space, screw the infusion adaptor onto the cannula until fingertight. Push the saline inflow tube firmly onto the infusion adaptor.

Testing the System's Operation

To check the instrument's operation, turn the Control Unit power switch to "on" (H). "MOTOR MISSING" and "FOOTSWITCH" may alternately appear on the Diagnostic Display if they are missing or incorrectly connected. Check for correct positioning of the Motor Select switch with the actual motor connected to the Control Unit. Confirm that the Footpedal cord is securely fastened to the Footswitch outlet. "Dyonics PS3500" should now appear on the Diagnostic Display.

The motor will not rotate when there is no blade in the motor and the Footpedal is depressed. The Diagnostic Display will indicate "NO BLADE".

Once a Dyonics blade has been properly secured in the PS3500 motor, the name of the blade will appear on the Diagnostic Display. Due to BSR, the blade speed will automatically return to the last selected speed within the pre-determined range for that blade style.

Depress the left and right side of the Footpedal and check that the blade goes in both the forward and reverse directions. The Diagnostic Display will indicate the correct direction of the blade. Visual confirmation of the blade direction should be consistent with the Diagnostic Display.

Depressing the center of the Footpedal will run the motor drive unit in "OSCILLATE" Mode. Depressing both sides of pedal will also run blades in oscillate mode. The Motor Drive unit will reach the selected speed during each oscillation. The oscillate interval will be shorter at slower speeds and longer at faster speeds due to the constant acceleration/deceleration of the Motor Drive unit.

NOTE: Some blades will not run in "REVERSE" or "OSCILLATE". Please refer to the blade chart for further information.

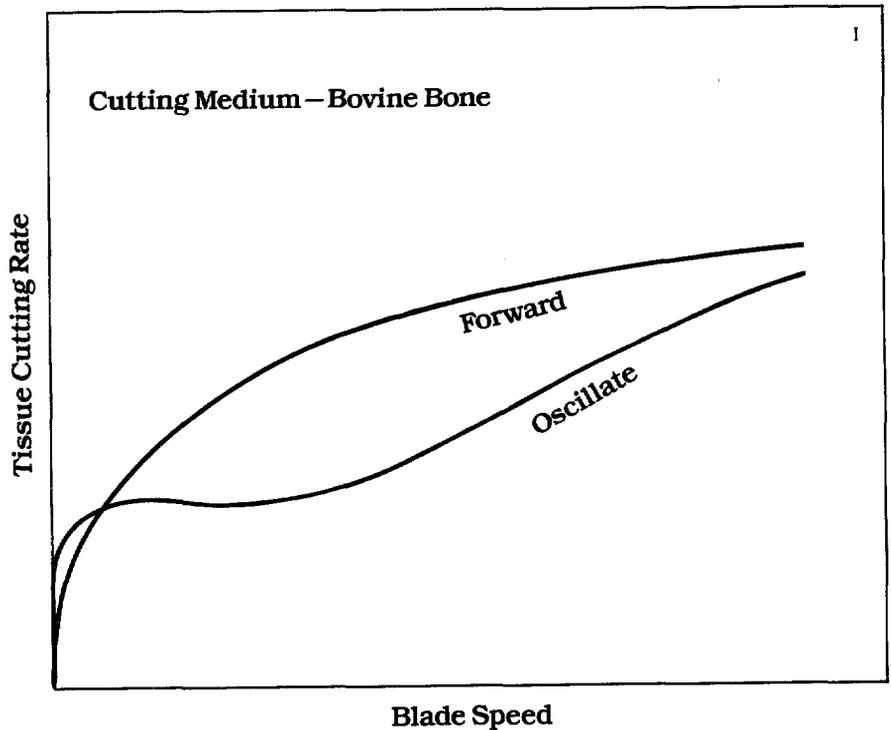
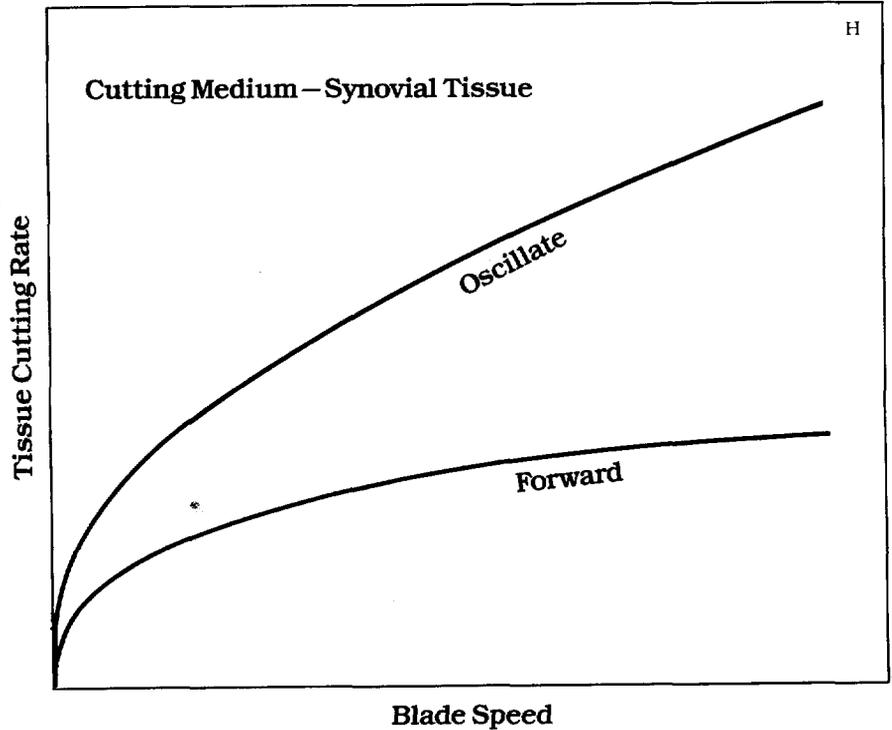
Blade Speed Ranges (rpm)

All Dyonics disposable and reusable blades have been extensively tested for safety and performance. Blade speed ranges have been pre-set on your PS3500™ System based on this information.

The tissue cutting performance was determined at various speeds for each blade. This information indicates that some blades are more efficient when they are cutting in the "OSCILLATE" mode (H). Others are more efficient when running "FORWARD" (I).

Blade speed performance data has been summarized on the following table. This data includes the pre-set speed ranges for each blade style and the direction each blade is allowed to rotate.

When the Universal Motor Drive is connected to the PS3500 Control Unit the Universal AutoSensor allows all of the PS3500 blades to run from 400 to 1400 rpm. When the Universal Motor Drive is connected to the Advanced Arthroscopic Surgical System, blades run at speeds indicated on the front panel of the AASS Control Unit.



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Blade Speed Summary Table

Blade style	Size (P/N)	Available speed range (rpm)	Blade direction
			Forward: F Reverse: R Oscillate: O Listed in order of efficiency
CUTTER*	3.5mm disposable (3439)	350-1400	O, F/R
	3.5mm reusable (3457)	350-1400	
	4.5mm disposable (3440)	350-1400	
	4.5mm reusable (3458)	350-1400	
	5.5mm disposable (3598)	350-1400	
	5.5mm reusable (3459)	350-1400	
TRIMMER	4.5mm disposable (3441)	350-2000	O, F/R
	4.5mm reusable (3460)	350-1400	
FULL RADIUS	3.5mm disposable (3442)	500-2800	O, F/R
	3.5mm reusable (3461)	500-2000	
	4.5mm disposable (3443)	500-2800	
	4.5mm reusable (3462)	500-2000	
	5.5mm disposable (3444)	500-2800	
	5.5mm reusable (3463)	500-2000	
TURBOWHISKER™	4.5mm disposable (3446)	500-2000	O, F/R
FULL RADIUS WHISKERS	3.5mm reusable (3468)	500-2000	
	5.5mm reusable (3469)	500-2000	
PROCUTTER™**	4.0mm disposable (3447)	500-3000	F/R, O
	4.0mm reusable (3472)	500-3000	
	5.0mm disposable (3448)	500-3000	
	5.0mm reusable (3473)	500-3000	
TURBOCUTTER™	3.0mm reusable (3470)	500-3500	F
	4.0mm disposable (3449)	500-3500	
	4.5mm reusable (3471)	500-3500	
TURBOTRIMMER™	4.5mm disposable (3529)	400-2800	O, F/R
ABRADER	4.0mm disposable (3450)	500-3500	F, R
	4.0mm reusable (3464)	500-3500	
	5.5mm disposable (3451)	500-3500	
	5.5mm reusable (3465)	500-3500	
ACROMIONIZER	4.0mm disposable (3452)	500-3500	F, R
	4.0mm reusable (3466)	500-3500	
	5.5mm disposable (3453)	500-3500	
	5.5mm reusable (3467)	500-3500	
AUTOSENSORS with Universal Motor Drive	Small Joint: reusable blades (3085)	300-1500	
	Mini: disposable blades (3576)	300-1500	
	Arthroplasty: reusable/disposable blades (3379)	400-1400	
	Shaver: reusable/disposable blades (3376)	120- 300	
	Universal: reusable/disposable blades (3492)	400-1400	
MINI MOTOR DRIVE	All Blades	350-3500	

*U.S. Patent Number: 4,274,414

**U.S. Patent Pending

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Maintenance and Service

Blade Assemblies

Each blade assembly is designed and manufactured to the close tolerances required for precise surgery. In order to maintain the assembly in that condition, you need to observe a few precautions.

CAUTION:

Don't let the rotating part of any blade or burr touch any metallic object, such as a cannula or arthroscope. Damage to both instruments is likely, and in severe cases the instrument tip can be fractured and possibly lodged in the joint. If such contact does occur, immediately examine the instrument tip for evidence of cracks, fractures, or dulling of the edge. Use an eye loupe to do this (J,K). If you are not certain the instrument tip is in good condition, return it to Dyonics Customer Service for evaluation. Provide a brief history of what happened.

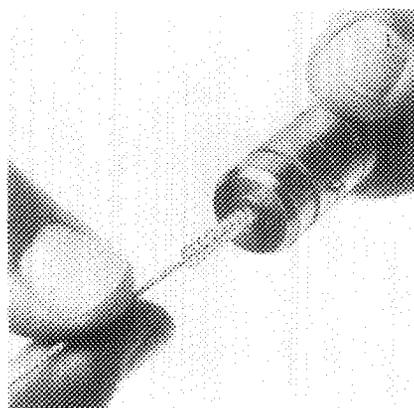
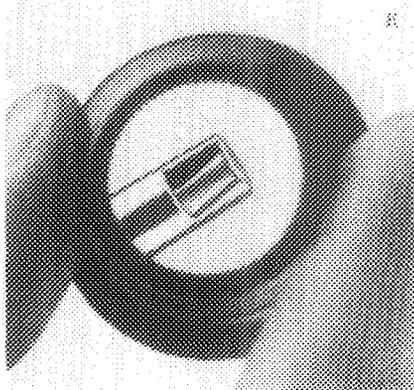
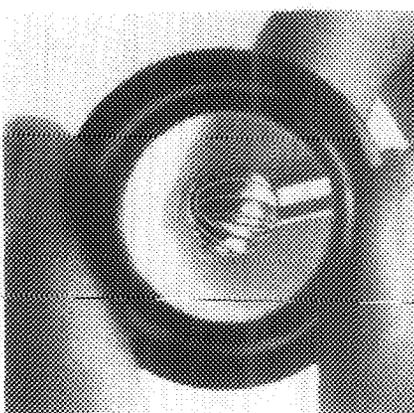
Reusable Blades

During Use:

Each reusable burr should remain sharp through several complete procedures. Inspect the burr tip after each procedure and replace the burr at the first sign of dullness.

Each reusable blade assembly should remain sharp through twenty or more procedures. The number of procedures varies with their duration and with the type of tissue cut. A blade can ordinarily be resharpened three times. Return blades to Dyonics for resharpening. Sharpening is authorized only if it is performed by Dyonics; any unauthorized sharpening voids the warranty. Improper service could pose a safety hazard.

Unlike burrs, cutting blades are intended only for soft tissue. They will be dulled more quickly, and can be damaged by contact with bone. When you return any blade assembly to Dyonics for service, be sure to include both the inner and outer assemblies. They can be identified by their matching serial numbers.



Cleaning and Lubrication

After use, remove the inner assembly from the outer tube and clean both with a brush (L). Then rinse thoroughly in water to remove saline and cleaning agents. Dry both sections inside and out. Lubricate the shaft of the inner assembly. Always lubricate before use or storage; failure to do so may result in rusting of the assembly.

Sterilization

All PS3500™ reusable blade assemblies and accessory hardware may be sterilized by ETO or steam, or soaked in disinfectant. For detailed instruction, see Guidelines for Cleaning and Sterilization in the back of this manual. **NOTE:** Extended soaking in solutions that contain instruments of dissimilar metals may lead to electrolytic corrosion.

Disposable Blades

Dyonics PS3500 disposable arthroscopic surgery blades must be used with the PS3500 System. Follow the instructions provided in each box of disposable blades for assembly.

Attach the blade directly to the PS3500 Motor by following the instructions in this manual. Dyonics disposable arthroscopy blades are intended for single use only. Do not re-sterilize or lubricate them.

NOTE: The blue "O" rings (P/N 3590) on PS3500 reusable blades should periodically be replaced to maintain good seals with the motor drive unit.

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PS3500™ and Mini Motor Drive Units

Cleaning and Sterilization

After each operation, disconnect the blade assembly from the PS3500 Motor Drive unit. Do not disconnect the power cord from the motor. Flush the Motor Drive unit thoroughly. Be sure to run water through the drain tube of the Motor Drive unit. Ensure that the flow control lever is open to allow flushing through the entire length of the fluid channel. You must clear all debris from these areas. For detailed instructions see Guideline for Sterilization in the back of this manual.

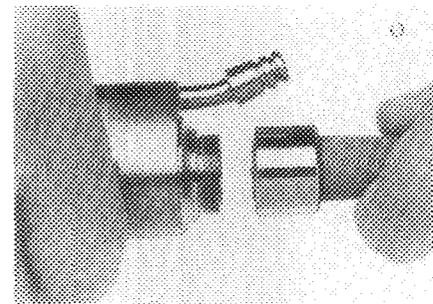
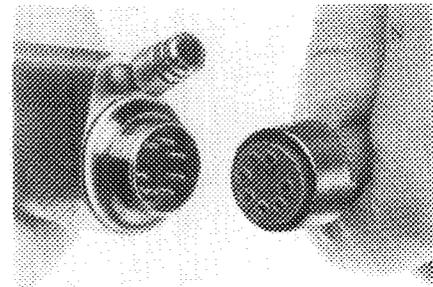
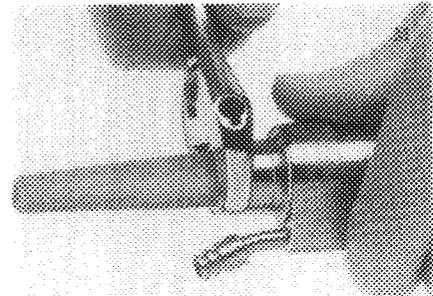
Do not disinfect or sterilize the Control Unit or the Foot Pedal.

After autoclaving your Motor Drive unit with its attached power cord, let them cool slowly to room temperature. This will take at least thirty minutes. Draping with a cold, damp sterile cloth can reduce the cooling time. Do not immerse a hot Motor Drive in cold water. A spare power cord is included with each system.

If the power cord is damaged it can be removed from the Motor Drive unit. Call our Sales Department to order a replacement power cord with installation instructions (part no. 3477).

Replacement Cord

1. Using standard adjustable wrench, grasp opposing flat surface of stainless steel ring at proximal end of Motor Drive unit and loosen by turning it counterclockwise. Then remove old cord from unit (M).
2. Before replacing the cord, clean and dry the connector pins and baseplate of the Motor Drive unit. Improper alignment of the connector pins and Motor Drive unit will result in damage to the electronics.
3. Carefully align the sockets of the replacement cord with the pins of the unit (N).
4. Push the cord on straight, slide the ring up to the Motor Drive unit, and turn the ring clockwise by hand. Slide the wrench over the opposing flat surfaces of the stainless steel ring and securely tighten (O).
5. Test your unit according to the operating instructions in this manual. Refer to "Assembling the System".



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Troubleshooting

When diagnostics say...	The problem may be...	And this may help...
MOTOR SELECTOR	The Motor Selector Switch is in between positions	Turn to the desired setting "PS3500™", "Mini", or "Universal"
FOOTSWITCH	The Control Unit senses the Footswitch plug loose or missing	Check to see if the Footswitch cord is securely attached
MOTOR MISSING	The Control Unit senses the PS3500 Motor Drive unit missing	Check to see if the PS3500 Motor Drive cord is securely attached
CHECK MOTOR (only when Footswitch is depressed)	<p>The Motor Selector Switch does not match the motor which has been plugged into the Control Unit</p> <p>If the Motor Selector and Motor Drive unit both match, the cord to the Motor Drive unit may be faulty.</p> <p>If the Motor Selector Switch and Motor Drive unit match and the cord has been replaced, and the message CHECK MOTOR persists</p>	<p>Change the Motor Selector Switch to the appropriate setting</p> <p>Replace the Motor Drive cord</p> <p>Call the Dyonics Service Department</p>
HI-TEMP	<p>The temperature sensor is indicating a high temperature condition in the Control Unit.</p> <p>After clearing the ventilation and cooling for 10 minutes HI-TEMP message remains on the Diagnostic Display</p>	<p>Check to make sure the ventilation from the back of the unit has not been covered. Clear drapes and reposition Control Unit to maximize ventilation.</p> <p>Call the Dyonics Service Department</p>
DATA NOT READY	The PS3500 Motor Drive is not sending blade code data to the Control Unit	Call the Dyonics Service Department
CONTROL UNIT ERI	Control Unit electronics failure. The Motor Drive unit will have no power	Call the Dyonics Service Department
DISPLAY ERROR	The fluorescent display is not ready to receive data	Reset system by turning power "off" then "on"
RESERVED	<p>An inappropriate blade has been inserted into the PS3500 Motor Drive unit</p> <p>If a Dyonics blade is attached to the PS3500 Motor Drive unit, the blade may have a faulty sensor</p>	<p>Check to insure only a Dyonics blade is in the PS3500 Motor Drive unit</p> <p>Replace the Dyonics blade with another blade. Return faulty blade to the Dyonics Service Dept.</p>
SWITCH ERROR	<p>The Speed Control Switches or Footswitch have become corroded</p> <p>The Footswitch has been replaced and the message SWITCH ERROR persists</p>	<p>Replace Footswitch</p> <p>Call the Dyonics Service Department</p>

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When diagnostics say... The problem may be... And this may help...

SERVICE REQ'D	The Control Unit has reached the suggested time table for the first service maintenance	Call the Dyonics Service Department
NO BLADE (only when Footswitch is depressed)	The Footswitch has been depressed when there is no blade in the PS3500™ Motor Drive unit or the Universal AutoSensor is missing from the Universal Motor Drive unit	Insert a Dyonics blade into the desired Motor Drive unit or insert the AutoSensor into the Universal Motor Drive unit
SYSTEM STATUS OK	No errors have been detected in the system. Message appears only when Speed Control Switches have been depressed simultaneously	
BLADE CODE ERROR	There is an electrofnics error in the Motor Drive which is unable to read the blade code	Call the Dyonics Service Department
The blade name in the Diagnostic Display does not match blade style in the PS3500 Motor Drive unit	A faulty sensor within blade	Replace blade with another of the same style
	The blade has been replaced. The Motor Drive may have faulty electronics	Call the Dyonics Service Department

Miscellaneous Troubleshooting

	Problem	Solution
If the video picture becomes cloudy due to poor suction	Suction Control Lever may be on minimum	Turn Suction Control Switch to maximum
	If Suction Control Lever is on maximum the blade/motor may be clogged with tissue	Disconnect blade and clear blade and Motor Drive unit
	If Suction Control Lever is on maximum and the blade/motor are clear but suction is still poor	Call the Dyonics Service Department
If the PS3500 System will not turn on	The Circuit Breaker Switch may have been turned off	Turn Circuit Breaker located on rear panel to the "ON" position
	If the Circuit Breaker is in the "ON" position and the system will not turn on with the Power Switch	Call the Dyonics Service Department
	If the Circuit Breaker continues to trip	Call the Dyonics Service Department
If the Diagnostic Display is not functioning in its normal manner	The Diagnostics may have to be reset	Turn the system "off" and then "on" with the Power Switch
If the Motor Drive unit abruptly loses power after continuous heavy usage	The over-current protector has been activated	The system will recover automatically and operate normally as soon as the heavy usage is reduced

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Cleaning, Sterilization, and Disinfection Guidelines

Component	Cleaning	Sterilization/Disinfection
Reusable Blades, Abraders	Clean with mild detergent and brush. Rinse thoroughly. Dry completely and lubricate before storing. During use, lubricate with lubricant compatible with chosen sterilization method	1st Choice—Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice—ETO per sterilizer instructions 3rd Choice—Soak in disinfectant per manufacturer's instructions
Trocars, Obturators, Cannulas	Clean with mild detergent and brush. Rinse and dry thoroughly	1st Choice—Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice—ETO per sterilizer instructions 3rd Choice—Soak in disinfectant per manufacturer's instructions
Disposable Blades, Abraders	Not intended for reuse	Safety may be compromised through the resterilization of a disposable blade. The plastic molding may be distorted and the lubricant between the inner and outer blade may be reduced after resterilization, compromising the proper rotation of the blade
Motor Drive unit PS3500™ Mini Universal	Clean unit thoroughly with soapy water. Unit may be immersed. Clean drain tube with brush. Rinse thoroughly with water. Do not use saline or solvents such as alcohol or acetone. Insure that the suction control valve is open	1st Choice—Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice—Steam by gravity displacement 250°F. 20 min. at temperature 3rd Choice—ETO per sterilizer's instructions 4th Choice—Soak in disinfectant per manufacturer's instructions
Control Unit	Disconnect from electrical power source. Wipe with clean, damp cloth. DO NOT IMMERSE	Do not sterilize or immerse in disinfectant solution

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Maintenance and Service

Blade Assemblies

Each blade assembly is designed and manufactured to the close tolerances required for precise surgery. In order to maintain the assembly in that condition, you need to observe a few precautions.

CAUTION:

Don't let the rotating part of any blade or burr touch any metallic object, such as a cannula or arthroscope. Damage to both instruments is likely, and in severe cases the instrument tip can be fractured and possibly lodged in the joint. If such contact does occur, immediately examine the instrument tip for evidence of cracks, fractures, or dulling of the edge. Use an eye loupe to do this (J,K). If you are not certain the instrument tip is in good condition, return it to Dyonics Customer Service for evaluation. Provide a brief history of what happened.

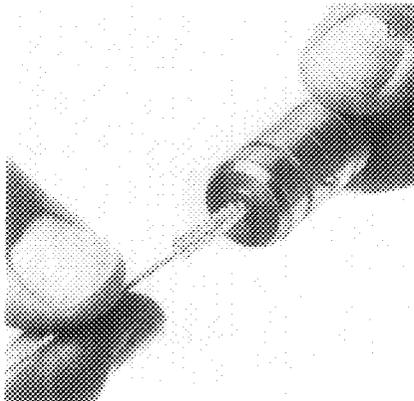
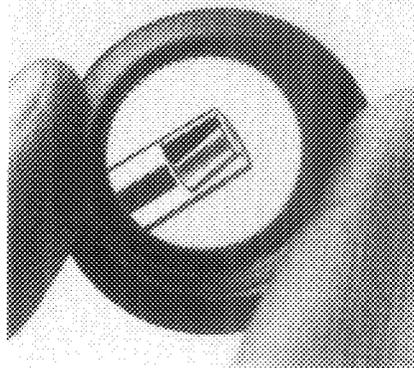
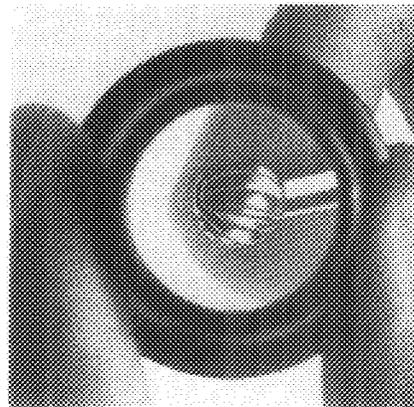
Reusable Blades

During Use:

Each reusable burr should remain sharp through several complete procedures. Inspect the burr tip after each procedure and replace the burr at the first sign of dullness.

Each reusable blade assembly should remain sharp through twenty or more procedures. The number of procedures varies with their duration and with the type of tissue cut. A blade can ordinarily be resharpened three times. Return blades to Dyonics for resharpening. Sharpening is authorized only if it is performed by Dyonics; any unauthorized sharpening voids the warranty. Improper service could pose a safety hazard.

Unlike burrs, cutting blades are intended only for soft tissue. They will be dulled more quickly and can be damaged by contact with bone. When you return any blade assembly to Dyonics for service, be sure to include both the inner and outer assemblies. They can be identified by their matching serial numbers.



Cleaning and Lubrication

After use, remove the inner assembly from the outer tube and clean both with a brush (L). Then rinse thoroughly in water to remove saline and cleaning agents. Dry both sections inside and out. Lubricate the shaft of the inner assembly. **Always** lubricate before use or storage; failure to do so may result in rusting of the assembly.

Sterilization

All PS3500[®] reusable blade assemblies and accessory hardware may be sterilized by ETO or steam, or soaked in disinfectant. For detailed instruction, see Guidelines for Cleaning and Sterilization in the back of this manual. **NOTE:** Extended soaking in solutions that contain instruments of dissimilar metals may lead to electrolytic corrosion.

Disposable Blades

Dyonics PS3500 disposable arthroscopic surgery blades must be used with the PS3500 System. Follow the instructions provided in each box of disposable blades for assembly.

Attach the blade directly to the PS3500 Motor by following the instructions in this manual. Dyonics disposable arthroscopy blades are intended for single use only. Do not re-sterilize or lubricate them.

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PS3500™ and Mini Motor Drive Units

Cleaning and Sterilization

After each operation, disconnect the blade assembly from the PS3500 Motor Drive unit. Do not disconnect the power cord from the motor. Rinse the Motor Drive unit thoroughly. Be sure to run water through the drain tube of the Motor Drive unit. Ensure that the flow control lever is open to allow flushing through the entire length of the fluid channel. You must clear all debris from these areas. For detailed instructions see Guideline for Sterilization in the back of this manual.

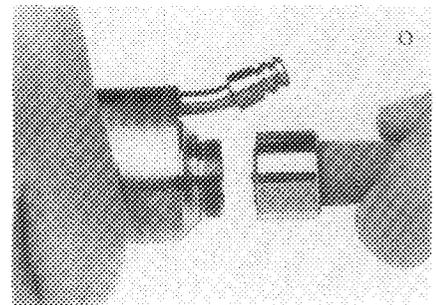
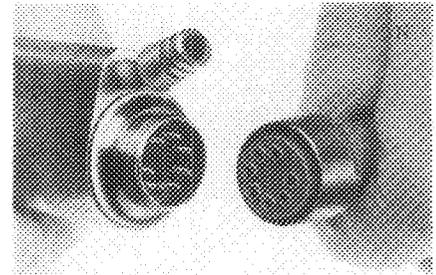
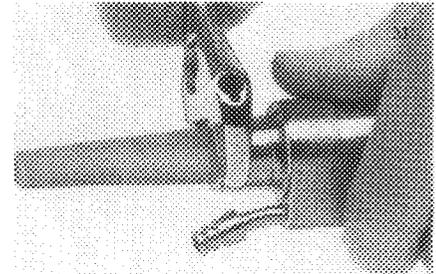
Do not disinfect or sterilize the Control Unit or the Foot Pedal.

After autoclaving your Motor Drive unit with its attached power cord, let them cool slowly to room temperature. This will take at least thirty minutes. Draping with a cold, damp sterile cloth can reduce the cooling time. Do not immerse a hot Motor Drive in cold water. A spare power cord is included with each system.

If the power cord is damaged it can be removed from the Motor Drive unit. Call our Sales Department to order a replacement power cord with installation instructions (part no. 3477).

Replacement Cord

1. Using standard adjustable wrench, grasp opposing flat surface of stainless steel ring at proximal end of Motor Drive unit and loosen by turning it counterclockwise. Then remove old cord from unit (M).
2. Before replacing the cord, clean and dry the connector pins and baseplate of the Motor Drive unit. Improper alignment of the connector pins and Motor Drive unit will result in damage to the electronics.
3. Carefully align the sockets of the replacement cord with the pins of the unit (N).
4. Push the cord on straight, slide the ring up to the Motor Drive unit, and turn the ring clockwise by hand. Slide the wrench over the opposing flat surfaces of the stainless steel ring and securely tighten (O).
5. Test your unit according to the operating instructions in this manual. Refer to "Assembling the System".



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Troubleshooting

When diagnostics say...	The problem may be...	And this may help...
MOTOR SELECTOR	The Motor Selector Switch is in between positions	Turn to the desired setting "PS3500™", "Mini", or "Universal"
FOOTSWITCH	The Control Unit senses the Footswitch plug loose or missing	Check to see if the Footswitch cord is securely attached
MOTOR MISSING	The Control Unit senses the PS3500 Motor Drive unit missing	Check to see if the PS3500 Motor Drive cord is securely attached
CHECK MOTOR (only when Footswitch is depressed)	The Motor Selector Switch does not match the motor which has been plugged into the Control Unit If the Motor Selector and Motor Drive unit both match, the cord to the Motor Drive unit may be faulty. If the Motor Selector Switch and Motor Drive unit match and the cord has been replaced, and the message CHECK MOTOR persists	Change the Motor Selector Switch to the appropriate setting Replace the Motor Drive cord Call the Dyonics Service Department
HI-TEMP	The temperature sensor is indicating a high temperature condition in the Control Unit. After clearing the ventilation and cooling for 10 minutes HI-TEMP message remains on the Diagnostic Display	Check to make sure the ventilation from the back of the unit has not been covered. Clear drapes and reposition Control Unit to maximize ventilation. Call the Dyonics Service Department
DATA NOT READY	The PS3500 Motor Drive is not sending blade code data to the Control Unit	Call the Dyonics Service Department
CONTROL UNIT ERI	Control Unit electronics failure. The Motor Drive unit will have no power	Call the Dyonics Service Department
DISPLAY ERROR	The fluorescent display is not ready to receive data	Reset system by turning power "off" then "on"
RESERVED	An inappropriate blade has been inserted into the PS3500 Motor Drive unit If a Dyonics blade is attached to the PS3500 Motor Drive unit, the blade may have a faulty sensor	Check to insure only a Dyonics blade is in the PS3500 Motor Drive unit Replace the Dyonics blade with another blade. Return faulty blade to the Dyonics Service Dept.
SWITCH ERROR	The Speed Control Switches or Footswitch have become corroded The Footswitch has been replaced and the message SWITCH ERROR persists	Replace Footswitch Call the Dyonics Service Department

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When diagnostics say... The problem may be... And this may help...

SERVICE REQ'D	The Control Unit has reached the suggested time table for the first service maintenance	Call the Dyonics Service Department
NO BLADE (only when Footswitch is depressed)	The Footswitch has been depressed when there is no blade in the PS3500™ Motor Drive unit or the Universal AutoSensor is missing from the Universal Motor Drive unit	Insert a Dyonics blade into the desired Motor Drive unit or insert the AutoSensor into the Universal Motor Drive unit
SYSTEM STATUS OK	No errors have been detected in the system. Message appears only when Speed Control Switches have been depressed simultaneously	
BLADE CODE ERROR	There is an electronics error in the Motor Drive which is unable to read the blade code	Call the Dyonics Service Department
The blade name in the Diagnostic Display does not match blade style in the PS3500 Motor Drive unit	A faulty sensor within blade The blade has been replaced. The Motor Drive may have faulty electronics	Replace blade with another of the same style Call the Dyonics Service Department

Miscellaneous Troubleshooting

	Problem	Solution
If the video picture becomes cloudy due to poor suction	Suction Control Lever may be on minimum	Turn Suction Control Switch to maximum
	If Suction Control Lever is on maximum the blade/motor may be clogged with tissue	Disconnect blade and clear blade and Motor Drive unit
	If Suction Control Lever is on maximum and the blade/motor are clear but suction is still poor	Call the Dyonics Service Department
If the PS3500 System will not turn on	The Circuit Breaker Switch may have been turned off	Turn Circuit Breaker located on rear panel to the "ON" position
	If the Circuit Breaker is in the "ON" position and the system will not turn on with the Power Switch	Call the Dyonics Service Department
	If the Circuit Breaker continues to trip	Call the Dyonics Service Department
If the Diagnostic Display is not functioning in its normal manner	The Diagnostics may have to be reset	Turn the system "off" and then "on" with the Power Switch
If the Motor Drive unit abruptly loses power after continuous heavy usage	The over-current protector has been activated	The system will recover automatically and operate normally as soon as the heavy usage is reduced

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Cleaning, Sterilization, and Disinfection Guidelines

Component	Cleaning	Sterilization/ Disinfection
Reusable Blades, Abraders	Clean with mild detergent and brush. Rinse thoroughly. Dry completely and lubricate before storing. During use, lubricate with lubricant compatible with chosen sterilization method	1st Choice – Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice – ETO per sterilizer instructions 3rd Choice – Soak in disinfectant per manufacturer's instructions
Trocars, Obturators, Cannulas	Clean with mild detergent and brush. Rinse and dry thoroughly	1st Choice – Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice – ETO per sterilizer instructions 3rd Choice – Soak in disinfectant per manufacturer's instructions
Disposable Blades, Abraders	Not intended for reuse	Safety may be compromised through the reesterilization of a disposable blade. The plastic molding may be distorted and the lubricant between the inner and outer blade may be reduced after reesterilization, compromising the proper rotation of the blade
Motor Drive unit PS3500™ Mini Universal	Clean unit thoroughly with soapy water. Unit may be immersed. Clean drain tube with brush. Rinse thoroughly with water. Do not use saline or solvents such as alcohol or acetone. Insure that the suction control valve is open	1st Choice – Steam (gravity displacement or prevacuum) 270°F. 3 min. at temperature 2nd Choice – Steam by gravity displacement 250°F. 20 min. at temperature 3rd Choice – ETO per sterilizer's instructions 4th Choice – Soak in disinfectant per manufacturer's instructions
Control Unit	Disconnect from electrical power source. Wipe with clean, damp cloth. DO NOT IMMERSSE	Do not sterilize or immerse in disinfectant solution

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Circuit Description

Overview:

PS3500™ is a computer modulated powered surgical system for arthroscopic use. The features include:

- Individual blade sensing
- Preferred speed memory
- Hi-powered operation
- Soft touch oscillate mode
- Audio/visual status indications
- Diagnostic and help system

120 Volt 60 Hz line power is supplied to the primary side of two low leakage isolated step down transformers T1 and T2 through a circuit breaker and a double pole illuminated On/Off switch. Two secondary low voltage outputs from T1 provide AC power for 5 V DC adjustable voltage regulator and a ± 15 V DC fixed voltage regulator for powering the control logic and front panel displays.

The 28 V AC power from T2 secondary provides power for a 26 V DC adjustable voltage regulator for powering the motor drives. A power transistor controlled from a microprocessor control loop adjusts the proper operating parameters for the motor speed and torque requirements. A power MOSFET H bridge driven by logic signals derived from the Footswitch, controls the motor direction and oscillate functions.

Motor Control Loop

The motor operational parameters are under microprocessor control. Acceleration and deceleration are controlled which gives the motor a soft feel and suppress inductive electrical spikes. Speed regulation is accomplished by monitoring the motor's condition every 1.5 milliseconds and adjusting its voltage accordingly. The microprocessor reads the voltage across a .1 ohm resistor in the power driver circuit via an eight bit analog to

digital converter. This voltage is directly proportional to load, and through the appropriate transfer functions, the motor output voltage is calculated and output through a ten bit digital to analog converter to the power driver circuitry. Also present in the power driver circuitry is an H switch for direction control of the motor.

Console Displays

The microprocessor lights the appropriate LED segments to display the speed range, the operating speed, and the relative position between maximum and minimum (bar graph).

RS-232

An interrupt controlled serial communications port is provided for system communications and peripheral device control.

Expansion Port

An expansion port is provided which brings all the microprocessor's data, address, and control lines to a connector for future use.

Switches (inputs)

All of the console and Footswitch switches enter through an eight bit port with opto isolators as necessary. This eight bit word represents all possible machine conditions. The Control Unit will accommodate three different motors which are selected by the console main selector switch. Once identified and the correct control parameters loaded, the Control Unit treats all motors the same. The various responses of the system are then delivered by the speed select switches

on the console and the Footswitch on the floor. All possible combinations of these inputs represent defined, legitimate control algorithms. The example: do nothing, oscillate, slow down while running in reverse, etc., are all independently functioning control routines.

Nonvolatile RAM

A permanent memory function is required to remember the last operating speed of each blade. A lithium battery powered 2 kilobyte random access memory chip was selected to provide all microprocessor random access memory needs. This chip has a 10 year life expectancy.

PROM

The Control Unit software resides in a 32 kilobyte PROM. The software consists of the control algorithm and blade data.

Audio Generator

A programmable complex sound generator is used to produce the variety of sounds which signal various diagnostic conditions.

Diagnostic Display

A 16 character by 1 line fluorescent display indicates all pertinent status conditions, i.e., motor system in use, blade, direction of rotation, speed up/slow down mode, help messages, warning messages, diagnostic error reports, test and calibration data, etc.

Diagnostic Port

Reserved for future use, these ports will help in trouble shooting the individual system components.

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Warranty

This instrument is guaranteed to be free from defects in material and workmanship for one year from the date of invoice. Alterations or repairs done by persons not specifically authorized by Dyonics, Inc. will void this warranty. The foregoing warranty shall apply only to the original buyer. In no event shall Dyonics be liable for any anticipated profits, consequential damages, or loss of time incurred by the buyer with the purchase or use of this equipment.

The above warranties are in lieu of all other warranties, either expressed or implied, including warranties of fitness or merchantability.

References

An Illustrated Guide to Abrasion Arthroplasty, As Described By Lanny L. Johnson, M.D. Courtesy of Dyonics, Inc., 1983

An Illustrated Guide to Arthroscopic Synovectomy, As Described By Thomas Rosenberg, M.D. Courtesy of Dyonics, Inc., 1984

An Illustrated Guide to Shoulder Arthroscopy, As Described By James R. Andrews, M.D. Courtesy of Dyonics, Inc., 1984

Arthroscopic Surgery of the Knee Instruction Manual, Robert Metcalf, M.D., Salt Lake City, Utah

Arthroscopic Surgery Principles and Practice, Lanny L. Johnson, M.D., 3rd Edition, The C.V. Mosby Company, 1986.

Arthroscopy, Richard L. O'Connor, M.D., J.B. Lippincott Company, 1977

Atlas of Arthroscopy, Masaki Watanabe, M.D., Sakai Takeda, M.D., and Hiroshi Ikeuchi, M.D., 3rd Edition, Igaku-Shoin, 1979

Diagnostic and Surgical Arthroscopy, the Knee and Other Joints, Lanny L. Johnson, M.D., 3rd Edition, The C.V. Mosby Company, 1985

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Attachment B: COMPONENT DRAWINGS

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*PERCUTANEOUS
ARTHROSCOPIC
MICRO-DISCECTOMY*

ATTACHMENT B:

INTRODUCTION SYSTEM - pg B2.

DISPO-PACK - pg B6.

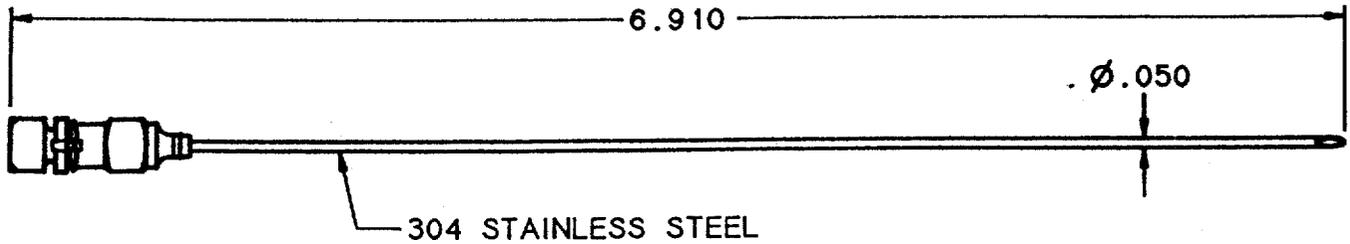
VISUALIZATION INSTRUMENTS - pg B7.

DEC 19 1989

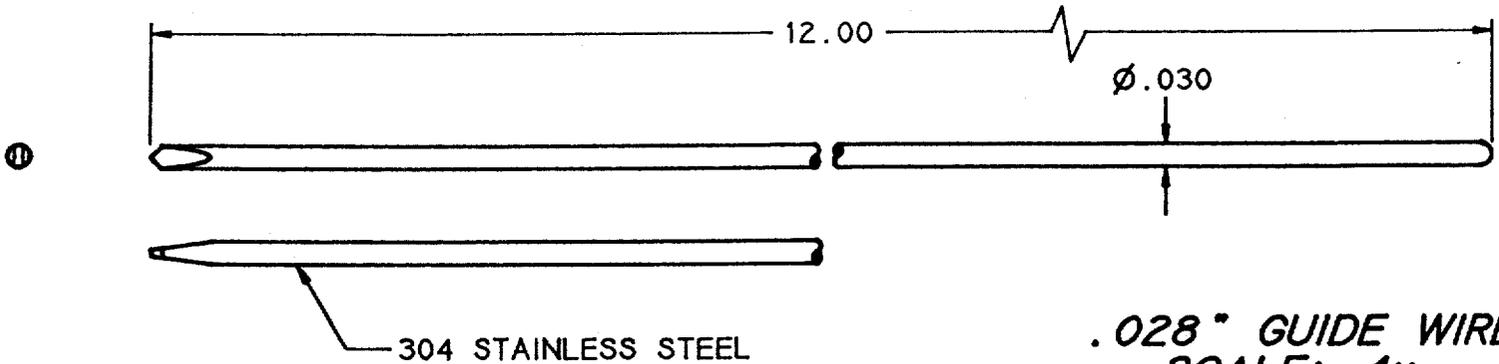
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Slp

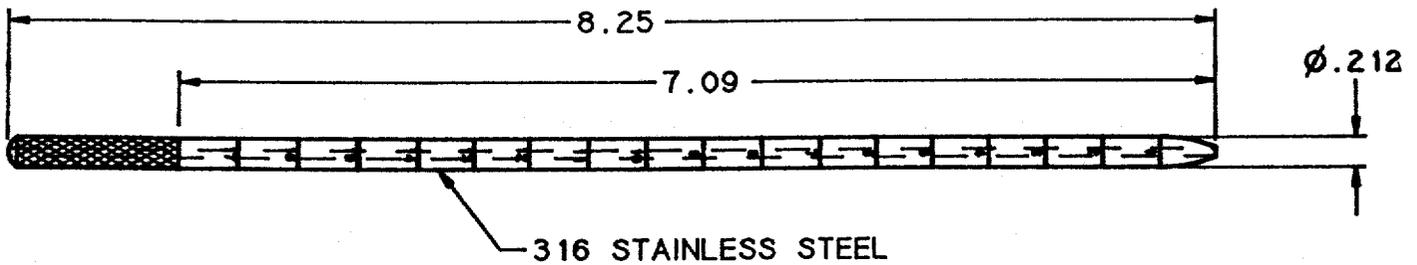
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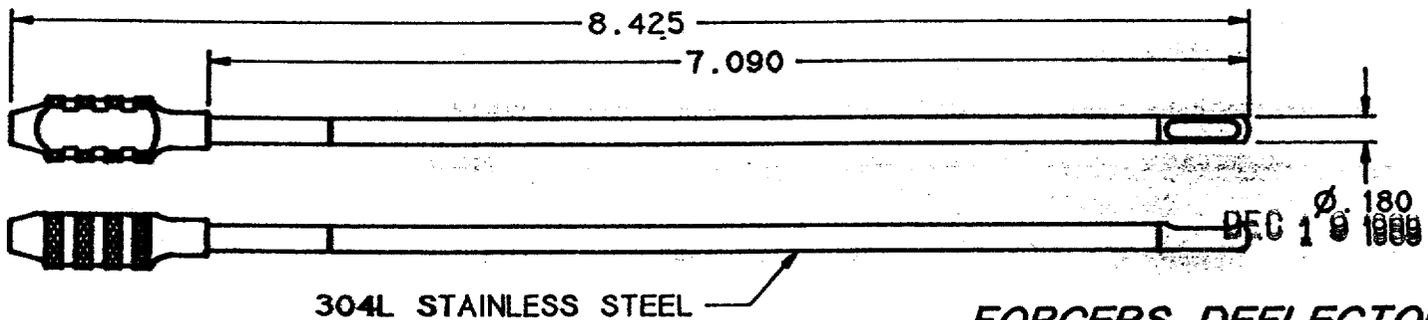
**18G SPINAL NEEDLE,
WITH STYLETTE**



**.028" GUIDE WIRE
SCALE: 4x**



**CANNULATED OBTURATOR
SCALE: 3/4x**

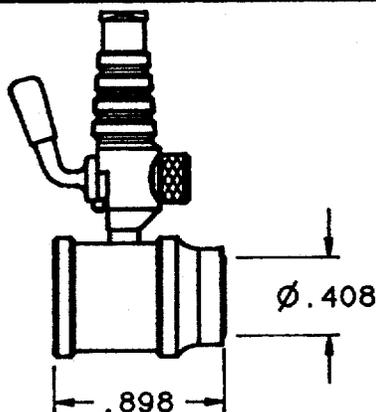
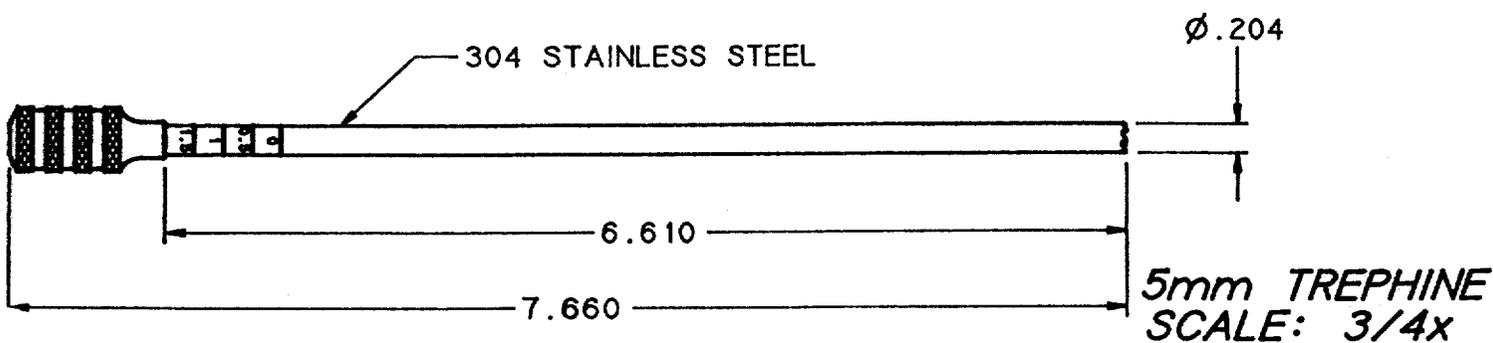
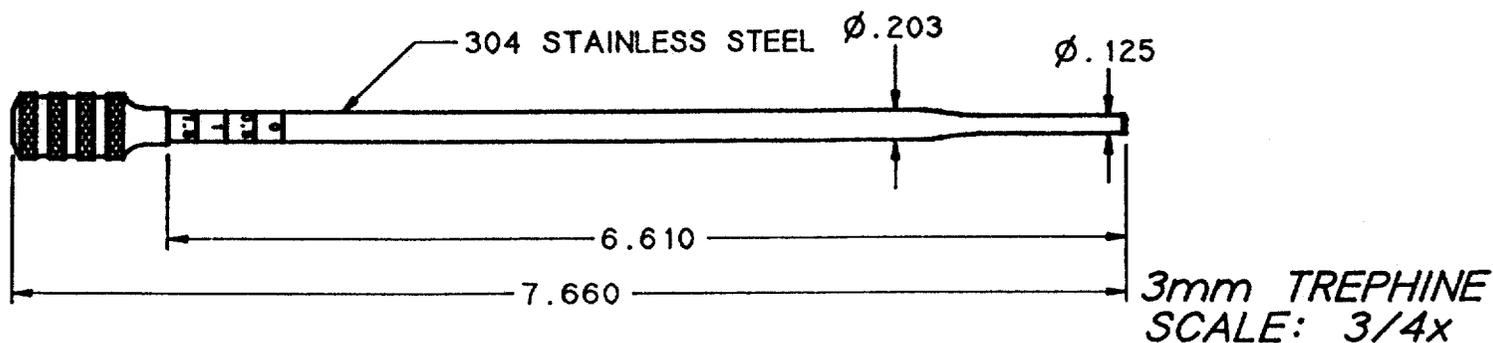


**FORCEPS DEFLECTOR TUB
SCALE: 3/4x**

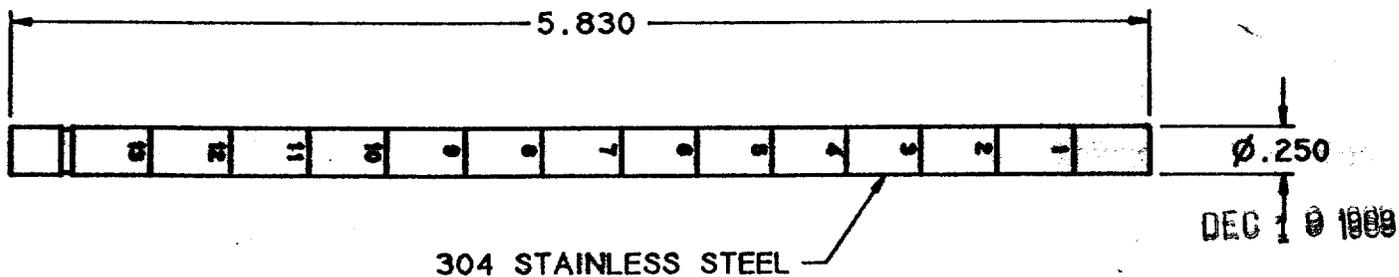
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INTRODUCTION SYSTEM



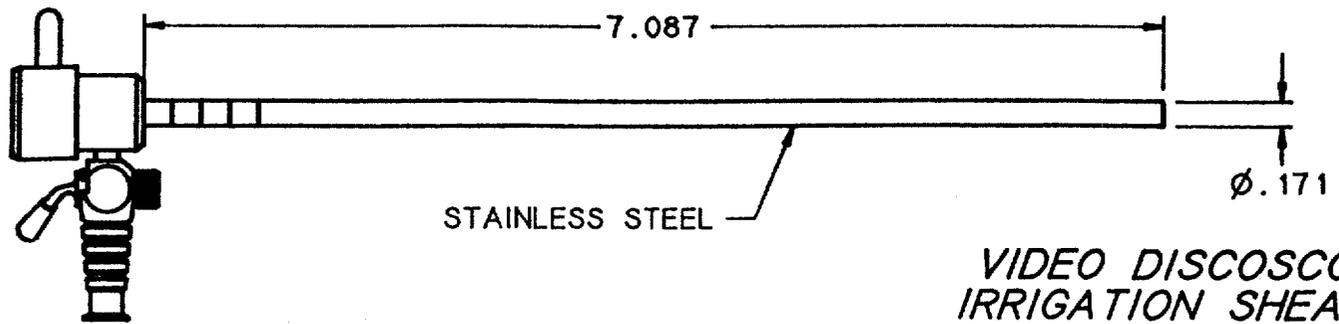
FLUID SEAL ADAPTOR



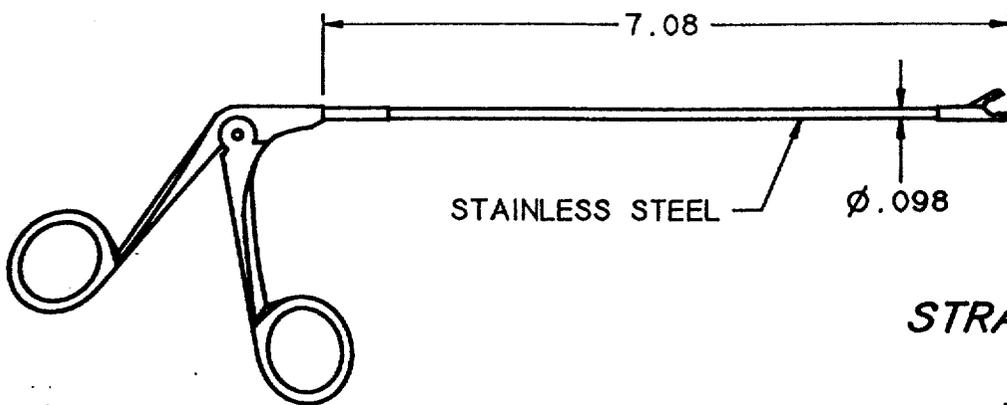
GRADUATED CANNULA

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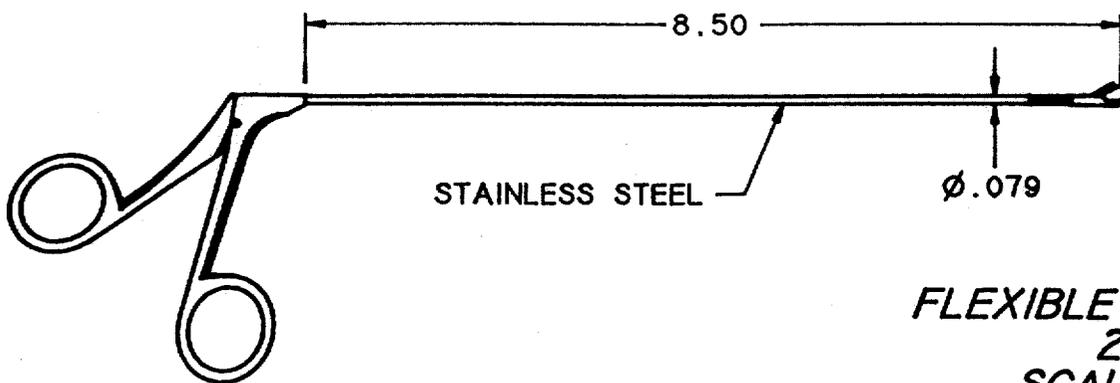
INTRODUCTION SYSTEM



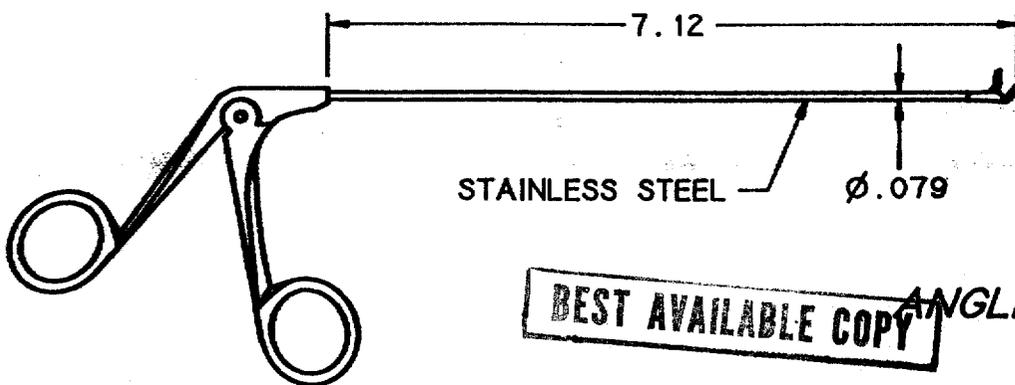
**VIDEO DISCOSCOPE
IRRIGATION SHEATH
SCALE: 3/4x**



**STRAIGHT CUP FORCEPS
RIGID, 3.0mm
SCALE: 1/2x**



**FLEXIBLE CUP FORCEPS
2.5mm
SCALE: 1/2x**

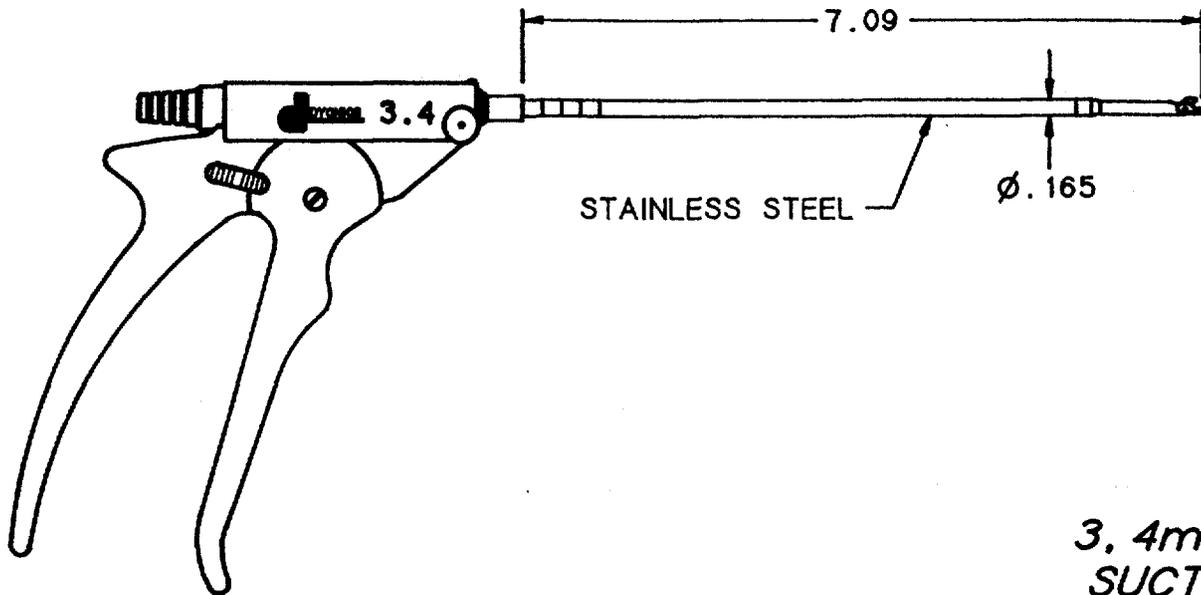


DEC 19 1989

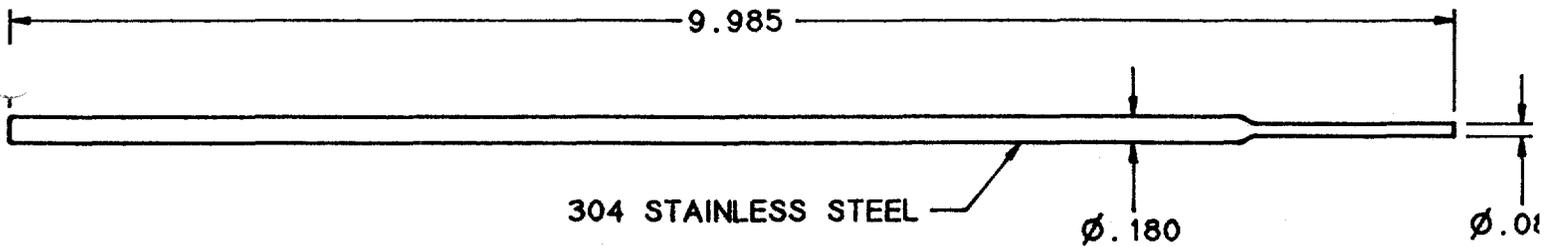
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**ANGLED UP CUP FORCEPS
2.0mm
SCALE: 1/2x**

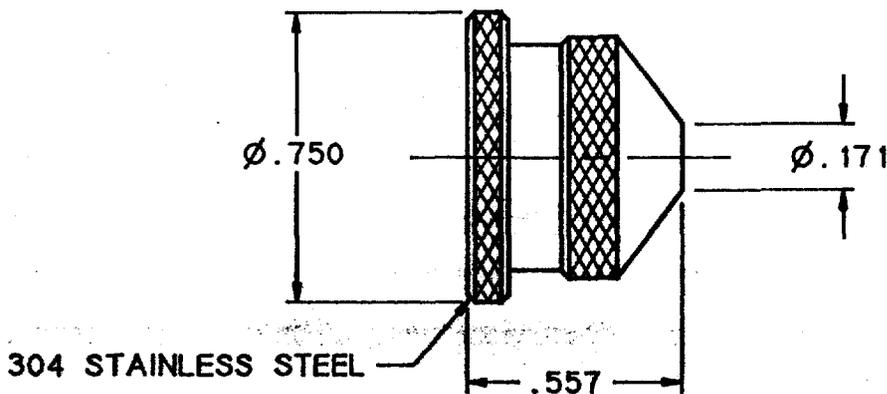
INTRODUCTION SYSTEM



**3.4mm DYOVAC™
SUCTION PUNCH
SCALE: 1/2x**



**MAGNETIC RETRIEVE
SCALE: 3/4x**

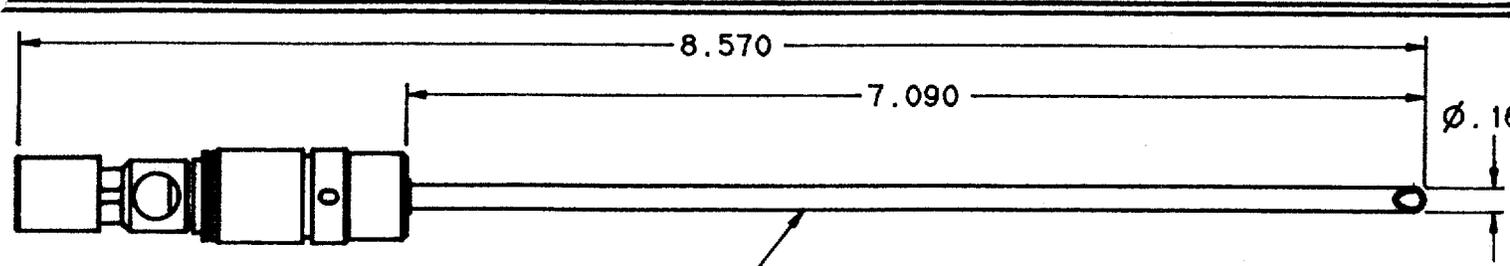


**CANNULA INSERTION
STOP
SCALE: 2x**

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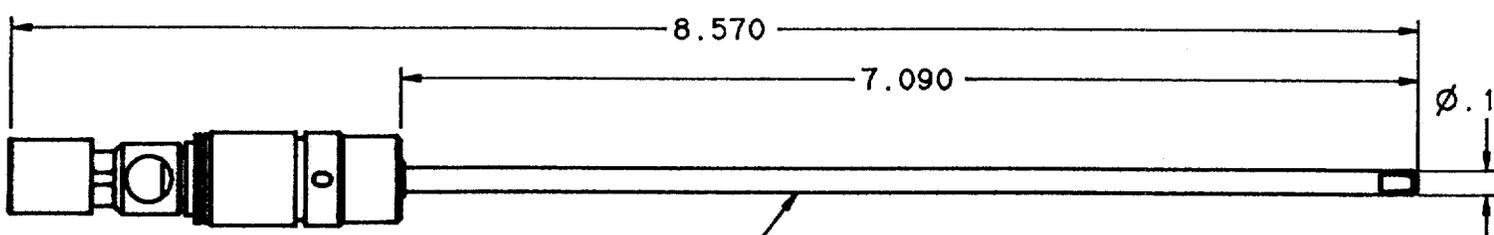
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DISPO-PACK



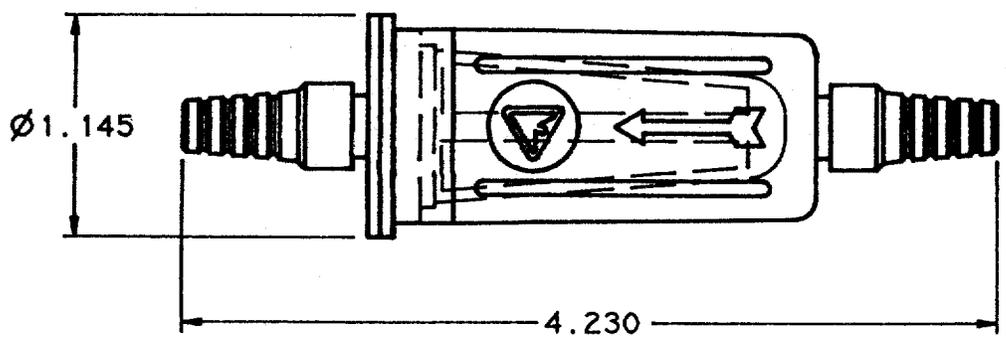
304L STAINLESS STEEL

**4.5mm FULL RADIUS
ARTHROSCOPY BLADE
SCALE: 3/4x**



304L STAINLESS STEEL

**4.5mm TRIMMER
ARTHROSCOPY BLADE
SCALE: 3/4x**



IN-LINE TISSUE TRAP

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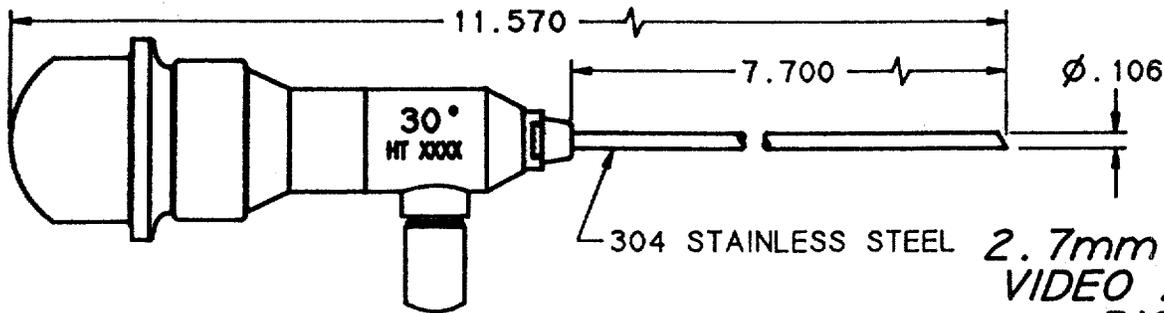
DEC 19 1989

61



VISUALIZATION INSTRUMENTS

B7



2.7mm x 30° x 45m
 VIDEO ARTHROSCOPE,
 DISCECTOMY
 SCALE: 3/4x

DEC 19 1989

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Dyonics, Inc., Andover, Massachusetts 01810
 (508) 470-2800 TWX 710-347-0337 FAX (508) 470-2193
 A MEMBER OF THE SMITH AND NEPHEW GROUP

62

Attachment C: TABLE OF CLASSIFICATION

<u>COMPONENT</u>	<u>CLASS</u>	<u>REFERENCE</u>
Spinal Needle	II	21 CFR 880.5570
Guide Wire	I	21 CFR 888.4540
Cannulated Obturator	I (Proposed)	53 FR 46040 (11/15/88)
Universal Cannula	I (Proposed)	53 FR 46040 (11/15/88)
Trephine	I	21 CFR 888.4540
Forcep Deflector Tube	I	21 CFR 888.4540
Tissue Removal Rod	I	21 CFR 888.4540
Cup Forcep	I	21 CFR 888.4540
Suction Punch	I	21 CFR 888.4540
Irrigation Sheath	II	21 CFR 888.1100
Video Discoscope	II	21 CRF 888.1100
Trimmer, Full Radius Blade	I (Proposed)	53 FR 46040 (11/15/88)
Tissue Trap	I	21 CFR 878.4800

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Attachment D: PROPOSED LABELING

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64

PROPOSED FDA 510K LABELING/INSTRUCTIONS FOR USE: PERCUTANEOUS
ARTHROSCOPIC MICRODISCECTOMY (PAMD)

1. Indications for Use: All patients are eligible for this procedure if they meet the following criteria:
 - A. Unremitting, persistent radiculopathy at L3-L4, L4-L5, or L5-S1 locations.
 - B. Failure to respond to conservative therapy.
 - C. Neurological impairment as reflected by sensory deficits, reflex abnormalities and motor weakness.
 - D. Correlative electromyography in the absence of correlative neurological deficits.
 - E. Positive tension signs.
 - F. Correlative imaging studies showing subannular herniated nucleus pulposus consistent with clinical findings.

2. Contraindications: Patients with the following history are not considered candidates for this procedure:
 - A. Sequestered disc herniation.
 - B. Bony lateral recess stenosis.
 - C. Spinal stenosis.
 - D. Pedicle induced nerve root kinking.
 - E. Patients with developmental abnormalities or tumors.
 - F. Patients with reherniation following laminectomy or chemonucleolysis.

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3. Radiological Findings: The following radiological techniques are to support the clinical findings and indications for use:

- A. Plain roentgenographic examination of the spine.
- B. Combination of computerized tomography (CT) scan and magnetic resonance imaging studies for localization of symptom producing discs.
- C. Myelographic studies as needed.

4. Precautions:

- A. Before using any of the systems for the first time, you should critically review all available information.
- B. Direct contact of the rotating cutting edge of blades with metal (i.e., cannula, arthroscope or other instrument) can cause damage to the instrument tip. This damage can range from slight distortion and/or dulling of the cutting edge to actual fracture of it's tip. If such contact should inadvertently occur, it is important to immediately stop using the blade and examine the instrument tip carefully for evidence of cracks or fractures. If there is any doubt about the condition of the blade assembly, the blade should be discarded or replaced with a new one. The discarded blade is to be returned to Dyonics for evaluation.
- C. The powered arthroscopy blades are intended for use with Dyonics Powered Surgical System. Please follow the instructions for use of the system before using the blades.

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D. This procedure requires Roentgenographic monitoring of instrument placement during each step.

5. Surgical Protocol:

A. Pre-operative: This surgical technique is to be performed in the operating room under a strict sterile environment. Prophylactic antibiotic is to be administered prior to the surgery and followed by 3 additional doses.

1. The patient is placed in the prone position on a radiolucent operative table with a well padded radiolucent frame extending from the ilium to the side of the chest wall. When discectomy at the L5-S1 disc space is performed, the lumbosacral spine should be kept flat or in flexion.
2. Skin preparation and surgical draping procedures are identical to those of an open spine procedure.
3. The C-Arm is positioned and covered by a sterile sheet.
CAUTION: Avoid blockage of the C-Arm with sterile sheets and drapes to assure reproducible antero-posterior and lateral imaging.
4. A marker is placed on the skin to determine the surgical level as is visualized in the anteroposterior X-ray projection.

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B. Surgical Introduction:

1. The procedure must be performed under local anesthesia. Intraoperative communication with the patient is essential. Anesthesia is obtained utilizing 1% xylocaine solution in the skin, subcutaneous tissue and fascia. The muscle layers are infiltrated with xylocaine containing epinephrin.

CAUTION: Periannular infiltration is to be avoided.

This will anesthetize the nerve root, pre-exposing it to injury.

2. Positioning the 18 gauge needle with stylette in place is performed with Roentgenographic assistance. The point of entry about 10cm from the midline, directed parallel to the vertebral end plates at an angle of 35 to 45 degrees. This results in approaching the annulus at it's posterior border or slightly anterior to it as verified by the lateral Roentgenographic projection. The anteroposterior projection is used to verify that the tip of the needle is immediately lateral to the superior articular process of the inferior vertebra or in alignment with the midportion of the pedicle. Resistance should be encountered when the needle approaches the annulus.

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3. Once the needle is properly positioned and verified as such through Roentographic projections, the stylette is withdrawn and replaced with the .028" Kirschner wire. Resistance should be felt when the wire engages the annulus.

CAUTION: Care must be taken to ensure the wire does not overpenetrate the annular fibers. A depth of 2mm is ideal.

4. Once the wire is properly placed, the needle is removed and the cannulated trocar is inserted over the wire. The wire should be fully withdrawn prior to full insertion of the cannulated trocar to avoid possible nerve entrapment or bend of the wire which makes it's insertion difficult. The trocar is then stabilized and held firmly for roentgenographic verification.

CAUTION: Angulation of the trocar during insertion should be avoided. Positioning is constantly checked roentgenographically at each step of the procedure.

5. The universal working sheath is passed over the trocar until it reaches the annulus. The trocar is then removed. A spinal needle is then walked around the inner diameter of the sheath contacting the annulus. This action should not produce radicular pain, thus indicating the absence of root entrapment.

CAUTION: If a nerve is entrapped, the needle will cause severe radicular symptoms. Repositioning of the instruments is then required.

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6. The sheath is positioned firmly against the annulus. The trocar is then fully withdrawn and the stopcock attachment secured to the proximal end of the cannula. The Videodiscoscope with the irrigation sheath attached is inserted into cannula. Saline is infused through the sheath while suction is applied via the cannula stopcock. The annulus is then examined to ensure no nerves are present or entrapped.
7. The Videodiscoscope and the stopcock attachment are removed and the annulus is anesthetized utilizing a small size cottonoid saturated with xylocain solution. The cottonoid is held against the annulus with the cup forceps.
8. The small diameter trephine is inserted into the cannula and rested firmly against the annulus. Annular fenestration is achieved through a clockwise circular motion of the trephine. The small diameter trephine is replaced with the large diameter trephine and fenestration repeated to ensure a sufficiently large opening to access the nucleus. The position of the sheath is roentgenographically monitored at each step to ensure proper placement.
9. The large trephine is removed and the stopcock attachment is again secured to the working sheath. The cup forceps are inserted to remove the freed nuclear material. Remove the stopcock attachment. The cannulated trocar is then inserted into the cannula thus entering the disc

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space. The cannula is then seated 2-3mm into the annulus. This is achieved through a circular twisting motion. Once secure, the trocar is removed and the stopcock reattached.

C. Surgical Removal:

1. The initial layers of the nucleus are removed utilizing manual instruments including the cup forceps and Dyovac Suction Punch for PAMD. The area is periodically irrigated with saline via the cannula stopcock. Location and position of the instruments within the nucleus is monitored roentgenographically.
2. The powered cutting blades are used in conjunction with the manual instruments to evacuate nuclear material and provide decompression of the intervertebral disc. Most of the fragments are reached in the area just adjacent to the open end of the working sheath. The depth of the instruments should be roentgenographically monitored.
CAUTION: Refer to operating instructions for proper use of Dyovac, VideoArthroscope and PS3500 Control Unit and other accessories.
3. The deflector tube with flexible forceps are used to reach material located posteriorly in the intervertebral disc. The progress of nuclear tissue removal is periodically monitored with the Videodiscoscope. ✓

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4. Once tissue removal is complete, the instruments are removed and the wound closed, a sterile dressing is applied.

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PERCUTANEOUS ARTHROSCOPIC MICRODISCECTOMY (PAMD)

A. Introduction System

1. 18G spinal needle with stylette
2. .028" K-wire
3. Cannulated trocar
4. Universal Working Sheaths
5. 3mm trephine
6. 5mm trephine

B. Tissue Removal Instruments

1. Cup forcep, 3.0mm, straight
2. Cup forcep, 2.5mm, flexible with deflector tube
3. Cup forcep, 2.5mm, angled up
4. 4.5mm Trimmer Blade, disposable
5. 4.5mm Full Radius Blade, disposable
6. 3.4 Dyovac Suction Punch for PAMD

C. Visualization Instruments

1. 2.7mm X 30 degree Videodiscoscope
2. 2.7mm X 70 degree Videodiscoscope
3. Irrigation sheath

D. Miscellaneous Support Instruments

1. Cleaning Wire/Magnetic retriever
2. Tissue trap
3. Sterilization tray

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DWG NO. 8008047

1020178 3/87

68076-01

BRUNING

Cat. # 3741
CANNULATED
OBTURATOR
for
P.A.M.D.

8008047

NOTES:

- 1. MATERIAL: 1-7/8 X 1-3/8 WHITE PAPER TABULATING LABEL, DIE CUT WITH ROUNDED CORNERS PER 8005761.**
- 2. MARKING TO BE VIA ELECTRONIC DATA PROCESSING PRINTER OR EQUIVALENT.**

REVISIONS						
DESCRIPTION	SYM.	ECO NO.	CHG'D BY	CHK'D BY	APPV'D BY	MICRO-FILM
REL TO						

MATERIAL:

FINISH:

3741

NEXT ASSEMBLY	WHERE USED
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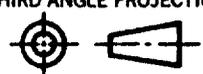
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DIMENSIONS AND TOLERANCES PER ANSI-Y-14.5M - 1982

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES.
 TOLERANCES ON:
 2 PLACE DECIMALS ±
 3 PLACE DECIMALS ±
 FRACTIONS ±
 ANGLES ±
 SURFACE FINISH ✓

THIRD ANGLE PROJECTION



DRAWN A. GANNON 11/16/89
CHECKED JGR 11/29/89
DESIGN APPV'L
MFG APPV'L
Q.A. APPV'L
MKT APPV'L MHE 11/21/89

DYONICS, INC. ANDOVER, MA 01810

TITLE:
 LABEL, PRODUCT IDENT,
 CATALOG NO. 3741

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SIZE	F.S.C.M. NO.	DWG NO.	REV
A	25471	8008047	1

SCALE: 1/1

SHEET	OF
	1

DO NOT SCALE DRAWING

74

ARTWORK PER 8007255
COLOR : BLACK

(4 x R .375)



Cat. No. 3739

DISPOSABLE PERCUTANEOUS LATERAL DISCECTOMY BLADE

4.5 mm DISCECTOMY TRIMMER BLADE

STERILE-DISPOSABLE

WARNING: These instruments are intended for single use only. DO NOT REUSE.
Sterilized by ETO. Sterility guaranteed if package has not been opened or damaged.

Lot

(11.125)

NOTES :

1. INDICATED DIMENSIONS ARE FOR FINAL TRIM AFTER SEALING.
2. MATERIAL : DUPONT 1073B TYVEK LIDSTOCK, HEAT SEALABLE TO PVC.
3. MARKING TO BE RESISTANT TO ETO STERILIZATION.
4. MARKING PER ARTWORK 8007258, COLOR PMS 542 BLUE EXCEPT AS OTHERWISE SPECIFIED.

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MATERIAL:

DIMENSIONS / PER ANSI-Y-14

UNLESS OTHERWISE SPECIFIED

DIMENSIONS AND TOLERANCE ON 2 PLACE DECIMALS 3 PLACE DECIMALS FRACTIONS ± ANGLES ± SURFACE FINISH

DO NOT SCALE

REVISIONS

DESCRIPTION:

SYM	ECO NO.	CHG'D BY	CHK'D BY	APPV'D BY	MICRO FILM
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ARTWORK PER 8007253
 COLOR : PMS 185 RED

JAN 2 1990

DYONICS, INC.
 160 Dascomb Road
 Andover, MA 01810 USA
 Tel. 800-343-5717
 In Mass 508-470-2800
 Made in U.S.A

Inner Blade Tube
 Outer Blade Tube

Peel

(2.125)

PROTOTYPE

DISCECTOMY

NEXT ASSEMBLY

WHERE USED

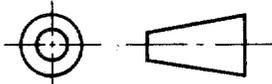
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 NOTE 2

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THIRD ANGLE PROJECTION



DYONICS, INC.

ANDOVER, MA 01810

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TITLE:

LIDSTOCK,
 DISPOSABLE BLADE TRAY
 4.5 DISCECTOMY TRIMMER

75

DRAWN *PMC* | 3/15/89

CHECKED

DESIGN APPV'L

MFG APPV'L

Q.A. APPV'L

SIZE F.S.C.M. NO. DWG NO. REV

B 25471 8007270

SCALE: 1/1

SHEET 1 OF 1

NOT DRAWING

ARTWORK PER 800
COLOR : BLACK

(4X R.375)



Cat. No. 3736

DISPOSABLE PERCUTANEOUS LATERAL DISCECTOMY BLADE

4.5 mm DISCECTOMY FULL RADIUS BLADE

STERILE-DISPOSABLE

WARNING: These instruments are intended for single use only. DO NOT REST
Sterilized by ETO. Sterility guaranteed if package has not been opened or damaged

Lot

(11.125)

NOTES :

1. INDICATED DIMENSIONS ARE FOR FINAL TRIM AFTER SEALING.
2. MATERIAL : DUPONT 1073B TYVEK LIDSTOCK, HEAT SEALABLE TO PVC.
3. MARKING TO BE RESISTANT TO ETO STERILIZATION.
4. MARKING PER ARTWORK 8007258, COLOR PMS 542 BLUE EXCEPT AS OTHERWISE SPECIFIED.

MATERIAL:

DIMENSIONS PER ANSI-Y-14

UNLESS OTHERWISE SPECIFIED

DIMENSIONS AND TOLERANCE ON 2 PLACE DECIMALS FRACTIONS ± ANGLES ± SURFACE FINISH

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DO SCALE

REVISIONS

DESCRIPTION:

SYM	ECO NO.	CHG'D BY	CHK'D BY	APPV'D BY	MICRO FILM

ARTWORK PER 8007253
 COLOR : PMS 185 RED

PROTOTYPE

JAN 2 1990

DYONICS, INC.
 160 Dascomb Road
 Andover, MA 01810 USA
 Tel. 800-343-5717
 In Mass 508-470-2800
 Made in U.S.A.

Inner Blade Tube
 Outer Blade Tube

Peel

(2.125)

DISSECTOMY

NEXT ASSEMBLY

WHERE USED

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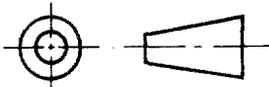
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 NOTE 2

FINISH:

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THIRD ANGLE PROJECTION



DYONICS, INC.

ANDOVER, MA 01810

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS IN INCHES.

UNLESS OTHERWISE SPECIFIED:
 DIMENSIONS IN INCHES.

DRAWN	
CHECKED	
DESIGN APPV'L	
MFG APPV'L	
Q.A. APPV'L	

TITLE:

BEST AVAILABLE COPY

LIDSTOCK,
 DISPOSABLE BLADE TRAY
 4.5 DISSECTOMY FULL RADIUS

Handwritten initials

SIZE F.S.C.M. NO. DWG NO. REV

B 25471 8007268

NOT A DRAWING

SCALE: 1/1

SHEET 1 OF 1

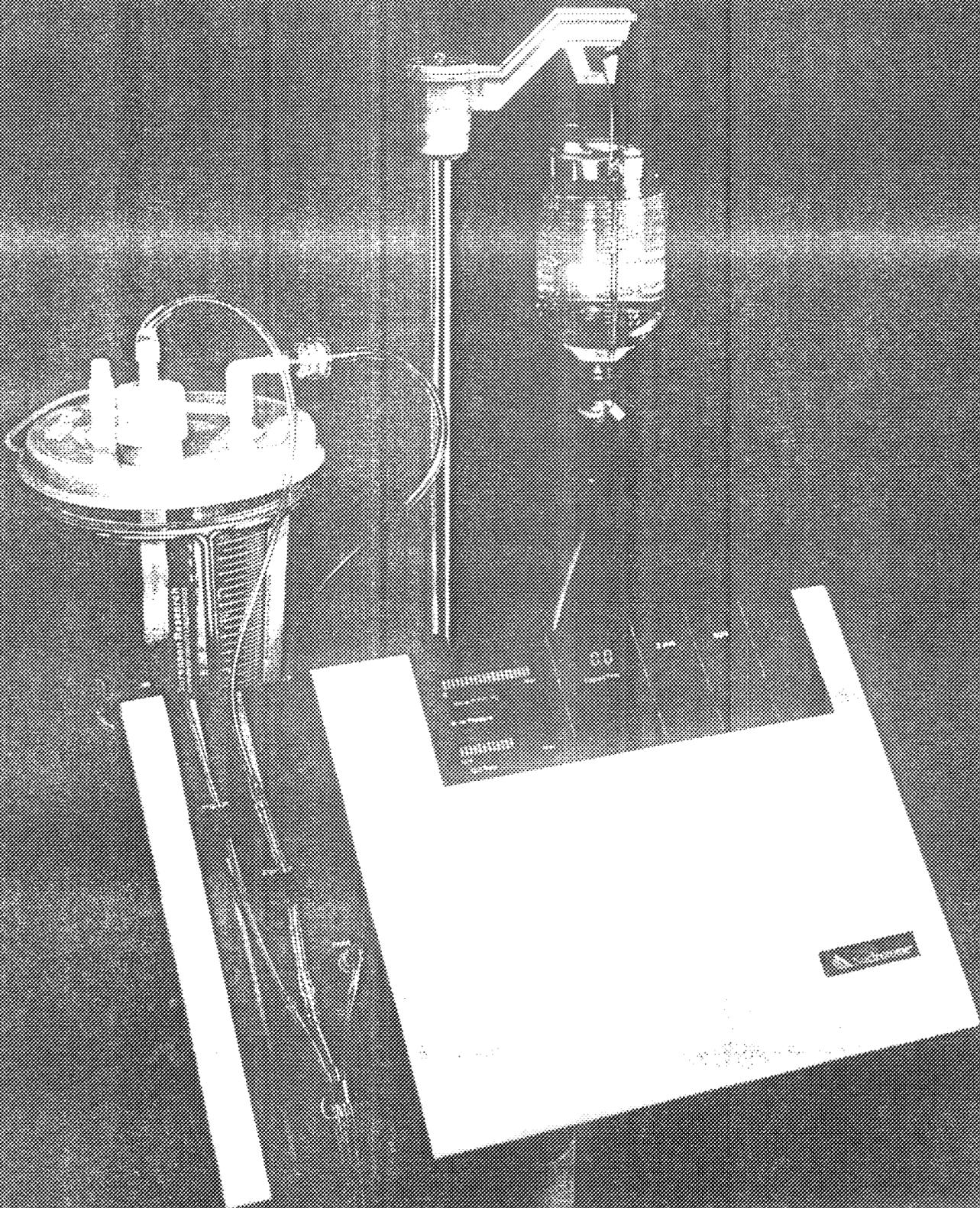
Attachment E: SURGICAL DYNAMICS SUPPORT LITERATURE

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Nucleotome® System

Automated Percutaneous Lumbar Discectomy



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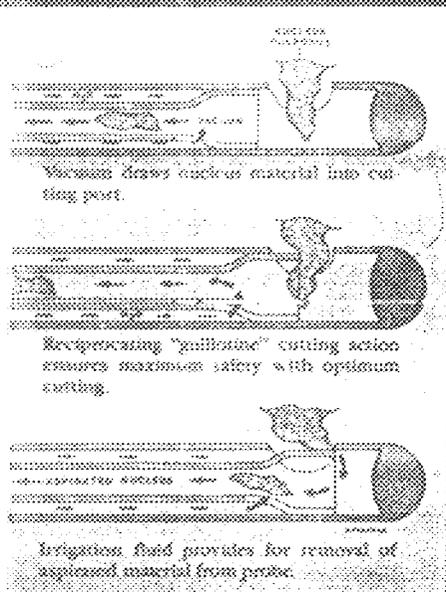
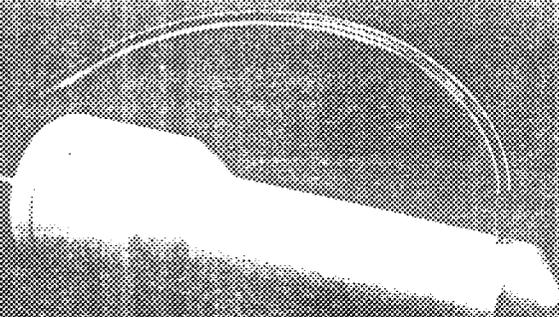
78

Surgical
Dynamics

The Nucleotome® System

The revolutionary Nucleotome® system utilizes a percutaneous approach for the rapid removal of nucleus pulposus from the lumbar disc, thereby reducing surgical trauma.

Studies have shown that patients meeting the clinical and surgical indications experienced immediate relief of symptoms. The automated action of the Nucleotome® probe provides the surgeon with a method of treatment that is reliable, efficient and easily controlled.

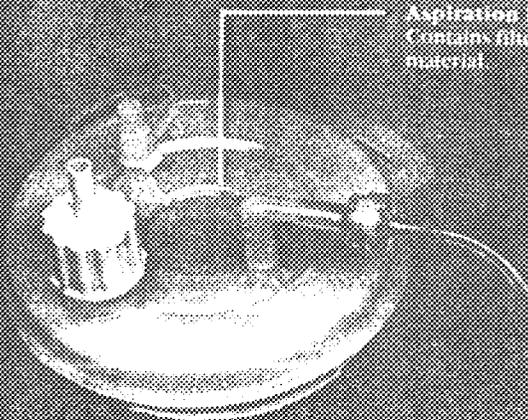


The Nucleotome® Probe

- Resects and aspirates nucleus pulposus in one step.
- Designed with a rounded, closed tip to prevent penetration of the annulus wall.
- Designed with reciprocating "guillotine" cutting action which ensures maximum safety with optimum cutting.
- Used under local anesthetic.
- Does not pose risk of anaphylaxis.
- Does not sacrifice bone stock.
- Reduces risk of postoperative complications.
- Does not routinely require sutures for skin closure.
- Provides the patient a more economic mode of treatment.

BEST IN CLASS

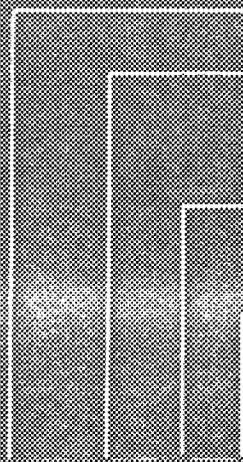
179



Aspiration Bottle
Contains filter to collect aspirated material.



Cut Rate Control Knob
Provides immediate control of the cutting rate of the probe.

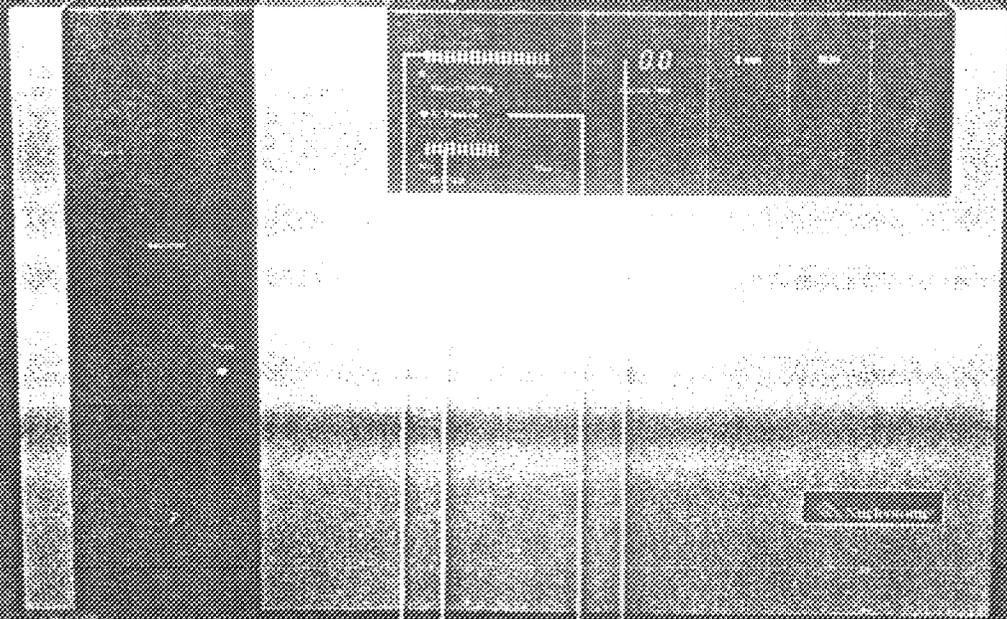


Reset Button
Resets the elapsed time indicator.

2mm/3mm Mode Switch & Display
Changes irrigation and aspiration timing sequence and displays mode.

Run/Load Mode Switch & Display
Load mode allows for convenient threading of tubing.

On/Off Switch
Visually indicates when console is on.



Vacuum Level Display
Visually indicates that adequate vacuum is available to aspirate material.

Cut Rate Display
Indicates cutting rate from minimum to maximum.

Elapsed Time Display
Indicates total time probe has been in use.

Air Pressure Display
Indicates that the pneumatic pressure is sufficient to drive system.

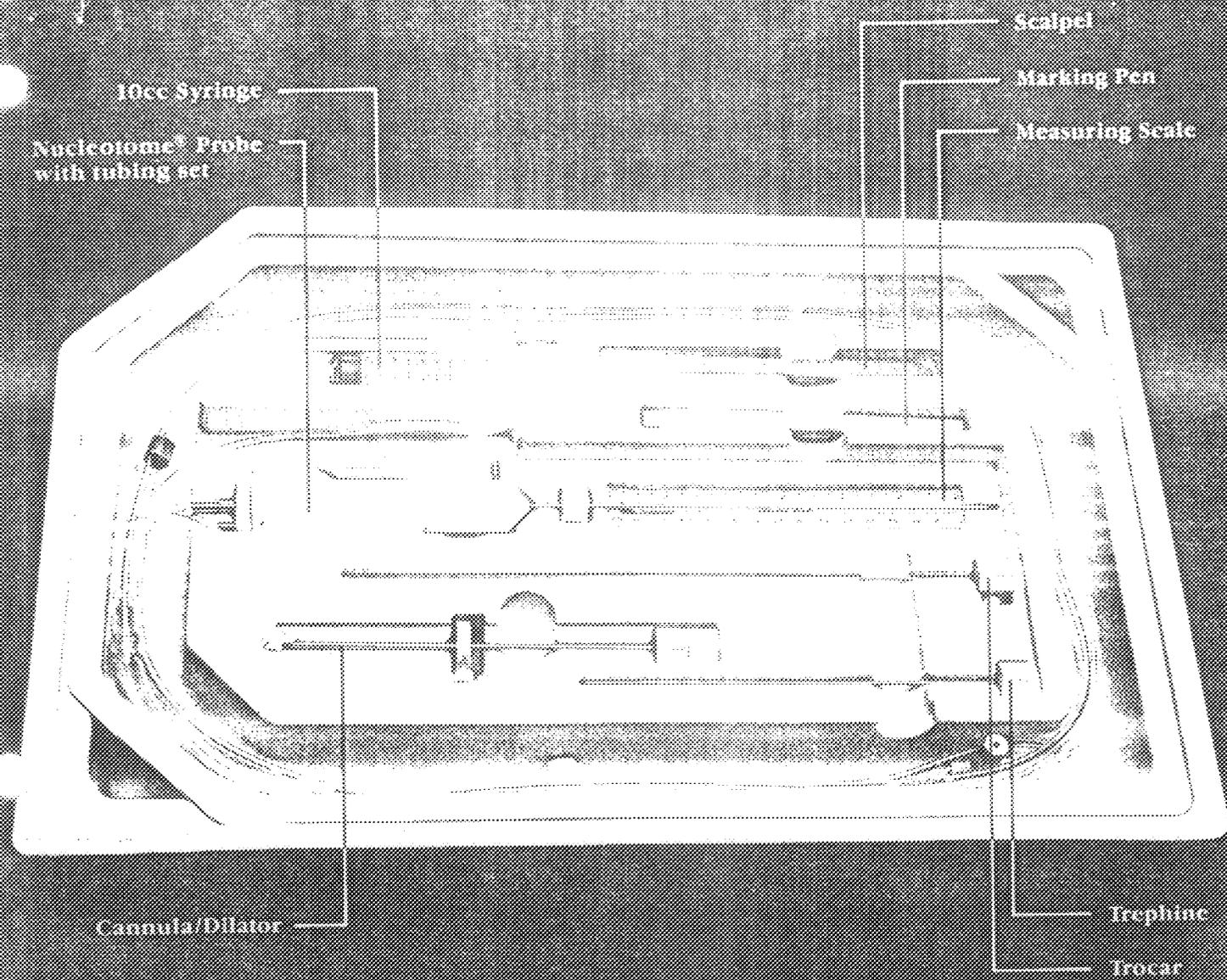
Features of Nucleotome® Console

- Illuminated displays
- Easy set-up procedure
- Portable/easy to store
- Quiet
- Reliable

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Nucleotome® Percutaneous Discectomy Kit
 (Disposable, single use only)



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Nucleotome® Console And Accessories

Catalog Number	Product Description
1-1000	Nucleotome Console Unit including Pneumatic Hose With Schrader Fitting and Foot Switch For Console
2-2000	2mm Percutaneous Discectomy Kit with Aspiration Bottle

Manufactured and distributed by



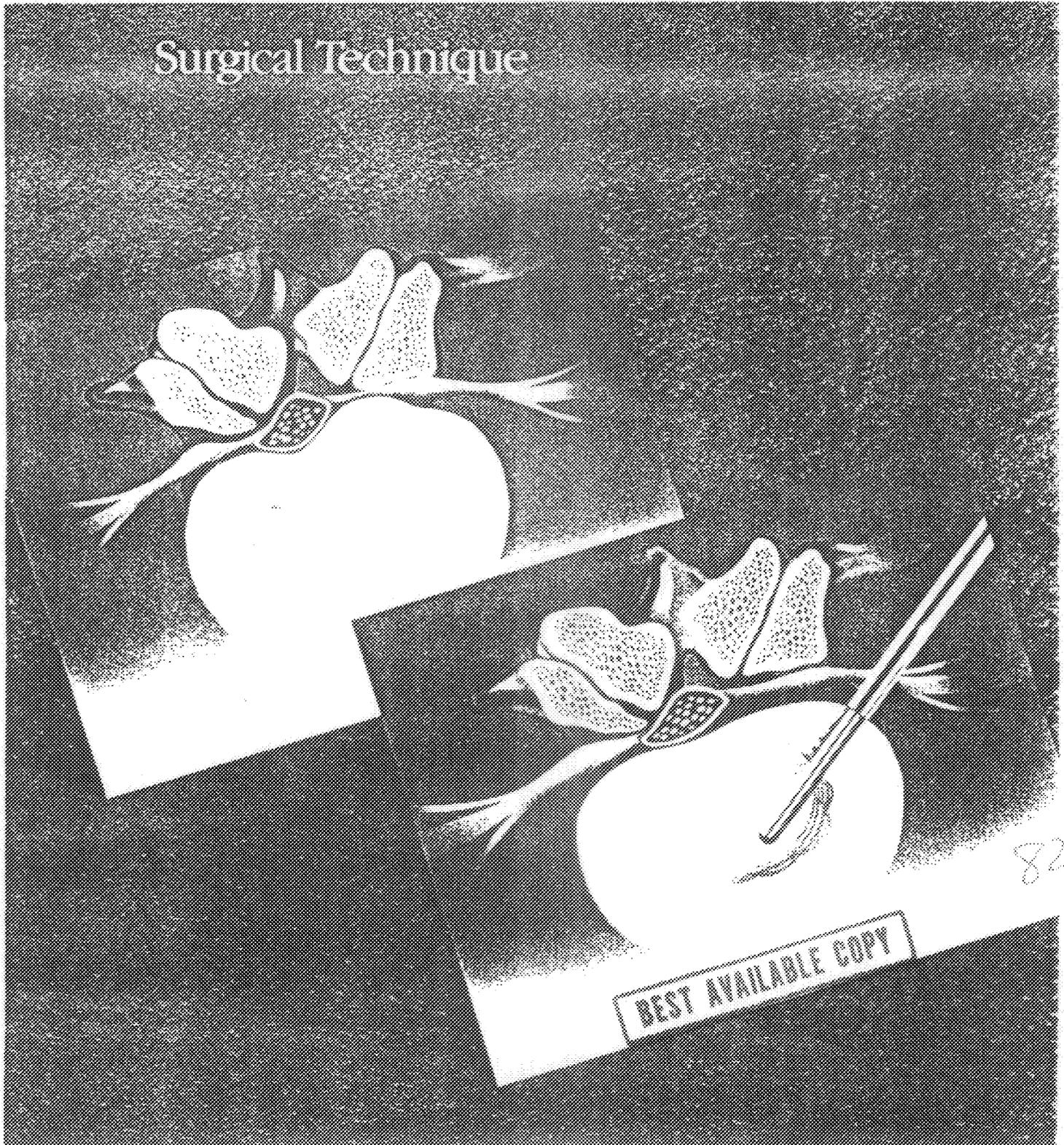
Surgical Dynamics, Inc. 14000 North Central Expressway, Dallas, Texas 75243

Surgical
Dynamics

Nucleotome[®] Procedure

Automated Percutaneous Lumbar Discectomy

Surgical Technique



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Automated Percutaneous Lumbar Discectomy

Surgical Technique Panel

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Courtney Brown M.D.
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James Morris M.D.
San Francisco, CA

G. William Davis M.D.
Nashville, TN

Joseph Schweigel M.D.
Vancouver, B.C.

Stephen Hochschuler M.D.
Plano, TX

Robert Watkins M.D.
Inglewood, CA

Vert Mooney M.D.
Dallas, TX

Leon Wiltse M.D.
Long Beach, CA

Neurosurgeons

Arthur Day M.D.
Gainesville, FL

Stewart Dunsker M.D.
Cincinnati, OH

Joseph Maroon M.D.
Pittsburgh, PA

Thomas B. Saul M.D.
Cincinnati, OH

Radiologist

Gary Onik M.D.
Pittsburgh, PA.

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Foreword

The initial treatment of choice for symptomatic herniated lumbar discs is the completion of at least six weeks of conservative treatment. However, for those patients who fail conservative treatment and require surgical intervention, the traditional surgical approach through a laminectomy or laminotomy, with or without use of a surgical microscope, has given way to less invasive surgical approaches.

Though the success rate of the traditional procedures has been reported as high as 90%, the risk of soft tissue injury, including epidural fibrosis, which can lead to long-term morbidity, has caused many surgeons to reconsider the risk vs. benefit of the more invasive traditional procedures.

The extent to which both physicians and patients sought an alternative to the traditional procedures was evidenced by the rapid acceptance of Chymopapain and Chemonucleolysis. Though less invasive, the serious complications associated with the injection of the drug including anaphylaxis, subarachnoid hemorrhage and transverse myelitis associated with paraplegia, have caused many physicians to discontinue performing Chemonucleolysis.

Considering the previous surgical approaches to the problem of symptomatic lumbar disc herniations, the designers of the Nucleotome System, in cooperation with leading Neurosurgeons, Orthopedic surgeons and Radiologists, set about the task of developing the Automated Percutaneous Lumbar Discectomy procedure. Commonly called the Nucleotome procedure, the procedure meets the following criteria:

- Is a conservative, yet effective surgical approach
- Is less invasive than Laminectomy or Microdiscectomy
- Does not sacrifice bone stock
- Does not violate the spinal canal, therefore, carries no risk of epidural fibrosis
- Reduces surgical trauma
- Reduces risk of intra-operative/postoperative complications
- Does not pose risk of anaphylaxis
- Uses local anesthesia
- Does not routinely require sutures for skin closure
- Can be performed as outpatient surgery under sterile technique
- Can provide immediate relief from symptoms
- Offers a more economic mode of treatment

Physicians performing the Automated Percutaneous Lumbar Discectomy procedure should be familiar with the physiology and pathology of the spine and qualified to perform spinal surgical procedures.

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Patient Selection Criteria

Automated Percutaneous Lumbar Discectomy is efficacious in treating patients with contained herniated nucleus pulposus who show evidence clinically and radiologically of nerve root impingement. The success of the procedure depends primarily on the correct selection of patients.

Poor selection of patients can result in failures in two ways: in choosing patients whose pain originates from a structure other than the disc, or in choosing patients whose pain originates from a herniated disc but who have complicating factors such as free fragments or severe bony stenosis.

Physical Examination

Clinically, the patient presenting leg pain greater than back pain is an excellent candidate for the procedure. On examination, the patient should have signs of nerve root irritation consistent with a herniated disc. These should include wasting, weakness and sensory or reflex alteration referable to a single root. The patient should exhibit a positive straight-leg raising sign.

Patients whose pain is intractable, regardless of position (lying, standing or sitting) or who present a crossed positive straight-leg raising sign, should be carefully evaluated radiographically as they may exhibit evidence of a free fragment.

Radiographic Study

Either a CT or MRI study should correlate with the patient's physical findings. These studies should provide contiguous 5mm axial sections from L-3 to S-1 with no associated gaps between disc spaces. Such studies are essential for excluding migrated free fragments of nucleus material.

Candidates for Automated Percutaneous Lumbar Discectomy should present on CT or MRI a focal herniation or bulge that shows an impression on the thecal sac which does not occupy more than 50% of the thecal sac and is consistent with the patient's symptomatology.



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Indications For Use

Patient selection criteria should include:

- Unilateral leg pain greater than back pain
- Paresthetic discomfort in a specific dermatomal distribution
- Positive straight leg raising test and/or positive bow-string sign
- Patient demonstrates possible neurologic findings (wasting, weakness, sensory alteration and reflex alteration)
- Patient shows no improvement after at least six weeks of conservative therapy
- A positive CT or MRI that shows a subligamentous herniation at the location consistent with clinical findings

Contraindications

Patients who present the following clinical and radiologic findings are not considered candidates for this procedure at this time:

- Radiologic evidence of a diffuse annular bulge extending out from the entire circumference of the vertebral body
- Radiologic evidence of severe lateral recess stenosis, calcified disc herniations, severe degenerative facet disease, and ligamentum flavum hypertrophy
- Radiologic evidence of free or extruded disc fragments within the spinal canal.
- Clinical evidence of significant progressive neurologic deficits and/or cauda equina syndrome
- The existence of other pathologies or conditions, such as fracture, tumor, pregnancy, or active infection that would place the patient at risk.

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Preoperative Planning

Preoperative Surgical Site Evaluation

Since it is desirable to position the Nucleotome probe as close to the herniation as possible, the selection of the entry site and route to the disc is always on the side of the herniation.

During the preoperative radiographic evaluation, it is important to review the proposed route from the posterolateral entry point to the disc to rule out the presence of retroperitoneal structures that may be in the path of the instrumentation (*Fig. A*). Recent radiologic literature indicates that marked posterior displacement of the colon can be found in approximately 4% of patients when they are placed in the prone position. Additionally, at higher levels, attention should be focused on the lower pole of the kidney and the sulcus of the pleural space to insure that they do not traverse the proposed path to the disc. Because numerous nerve fibers of the lumbar plexus traverse the psoas muscle, an entry point that avoids going through this muscle should be selected.

To avoid these retroperitoneal structures, a single non-magnified CT scan slice of the whole abdomen through the involved disc should be obtained. This slice can be taken at the same time as the diagnostic scan, but must be taken with the patient in the prone position, even if the procedure is to be later performed with the patient in the lateral position. The CT scan will enable you to select the exact entry site for the introduction of the FlexTrocator, as well as review the path to the concerned disc (*Fig. B*).

Mobile Fluoroscopic Equipment

The safety of the procedure relies chiefly in guiding the Nucleotome into the disc space and correctly confirming its location. The emphasis of the technique, therefore, is on the radiologic localization and guidance of the instruments into the disc. The C-arm fluoroscope with image intensification should provide clear and sharp images in AP, lateral and oblique views.

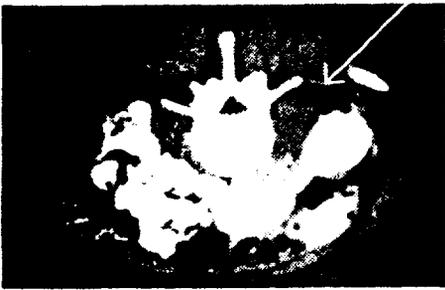


Fig. A.

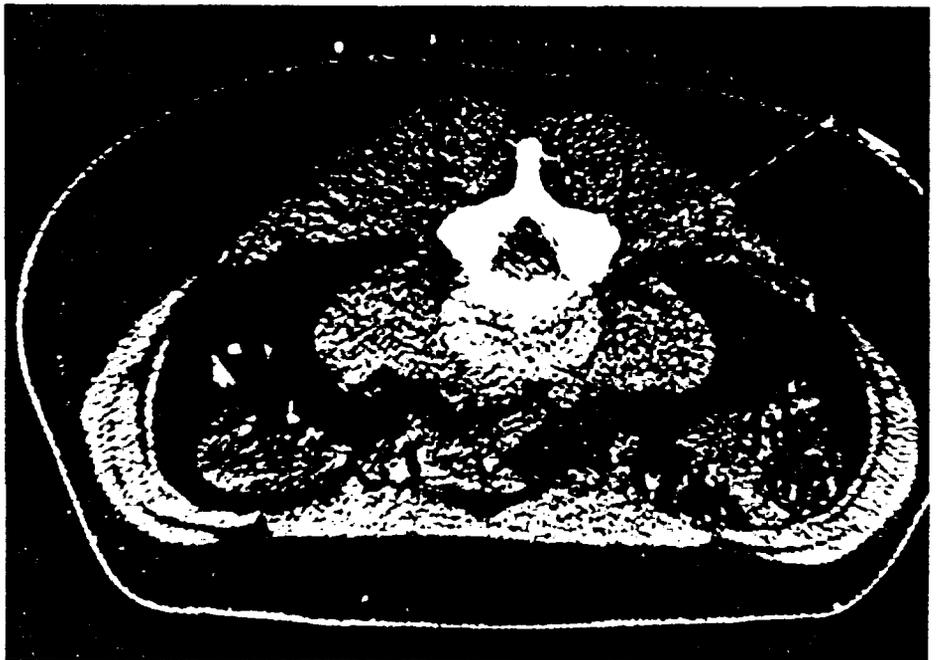


Fig. B.

Surgical Technique at L1-L5 Levels

Patient Positioning

The Nucleotome procedure is performed on a fluoroscopic table with the patient positioned in either the prone or lateral decubitus position. When the patient is placed in a prone position, pressure points should be cushioned and the patient should be flexed to decrease the lumbar lordosis and open the disc spaces posteriorly.

If the procedure is to be performed with the patient in the lateral decubitus position, in addition to making sure that the patient is flexed, care must be taken to stabilize the patient and prevent rotation of the shoulders and hips during the procedure. Such rotation can cause misinterpretation of the actual instrument placement when viewed in the AP view. When the patient is positioned correctly, on the AP view the spinous process is midway between the pedicles (*Fig. C*). If the patient is incorrectly positioned, the patient should be rotated into the correct position and secured.

When positioning the fluoroscope for the procedure in the lateral view, the sacrum should first be identified and then, using continuous fluoroscopy, the unit is moved up to the concerned disc space. Due to the limited field of view provided on fluoroscopic units, failure to first identify the sacrum may result in the misidentification of the concerned disc.



Fig. C.

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Surgical Technique at L1-L5 Levels

FlexTrocar™ Placement

A 3mm skin incision is made at the entry point and the FlexTrocar is inserted on the side of the herniation. A posterolateral approach is used, traversing the low back musculature and avoiding other retroperitoneal structures. In order to avoid touching the nerve root during FlexTrocar placement, the insertion is stopped short of the annulus and the position of the FlexTrocar tip is checked on the fluoroscope.

The insertion of the FlexTrocar is initially monitored fluoroscopically in the lateral view (*Fig. 1*). In this view, the FlexTrocar should be parallel to and midway between the vertebral body endplates with the tip of the FlexTrocar directed toward the center of the disc. The tip should be touching the posterior vertebral body line when the "gritty" sensation of touching the annulus is felt. If the FlexTrocar tip is anterior to the posterior vertebral body line when the annulus is felt, the trajectory is too anterior and the FlexTrocar should be withdrawn and redirected.

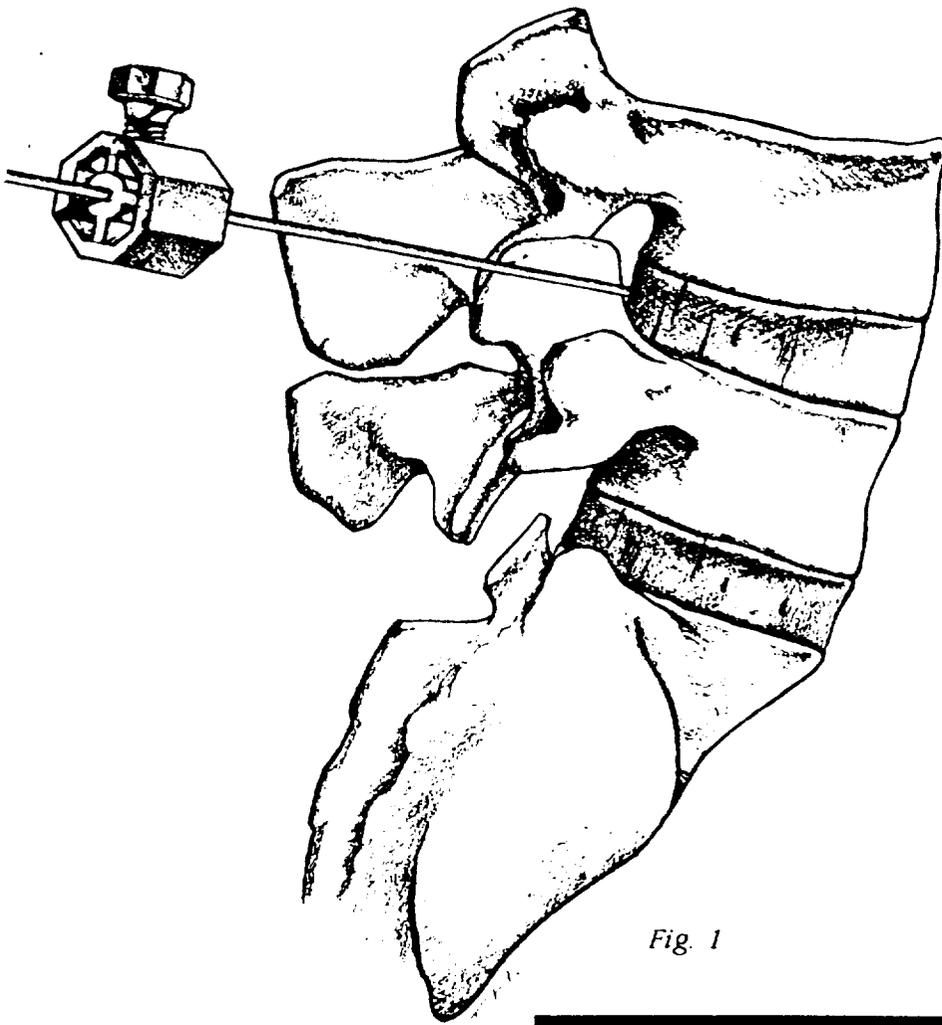
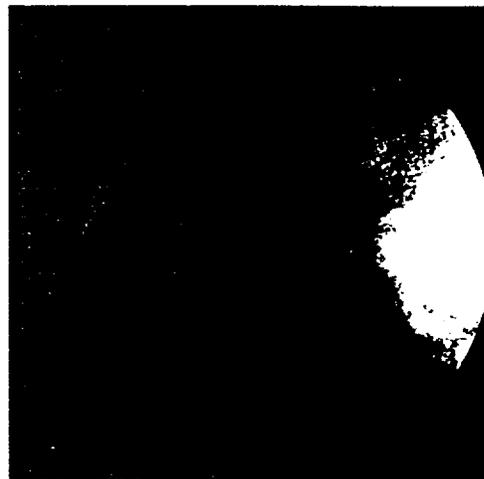


Fig. 1



NOTE:

During FlexTrocar placement, the patient is continually monitored for any sign of radicular pain. If radicular pain is experienced, the FlexTrocar should be withdrawn and redirected. The occurrence of radicular pain usually indicates that the nerve which is coursing anteriorly and inferiorly has been approached due to a superior or anterior FlexTrocar placement.

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Surgical Technique at L1-L5 Levels

When the annulus is felt and the tip of the FlexTrocar is at the posterior vertebral body line, the AP view is then obtained to confirm that the FlexTrocar is not traversing the thecal sac. In the AP view, the tip of the FlexTrocar should be lateral to a line that connects the medial borders of the pedicles (*Fig. 2*). Since the thecal sac lies medial to this line, if the tip of the FlexTrocar is lateral to the line and is touching the annulus, the FlexTrocar will not traverse the thecal sac when it is advanced to the center of the disc. When the tip of the FlexTrocar is in the correct position, it is advanced to the center of the disc.

The position of the FlexTrocar within the disc is confirmed in both AP and lateral views. The knob attached to the FlexTrocar is then removed (*Fig. 3*).

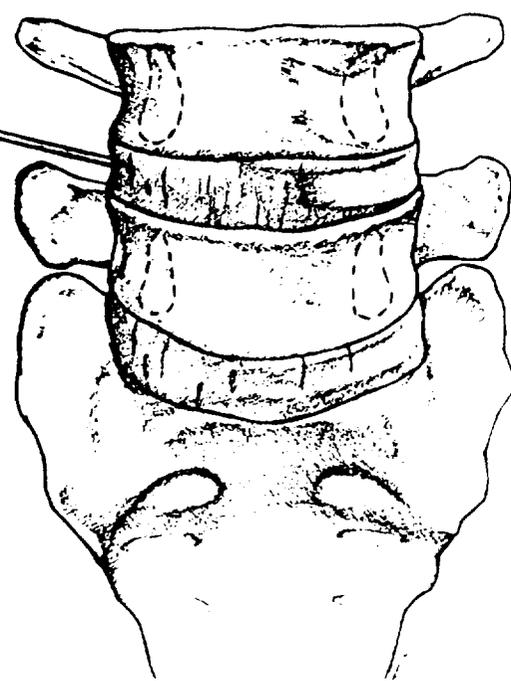
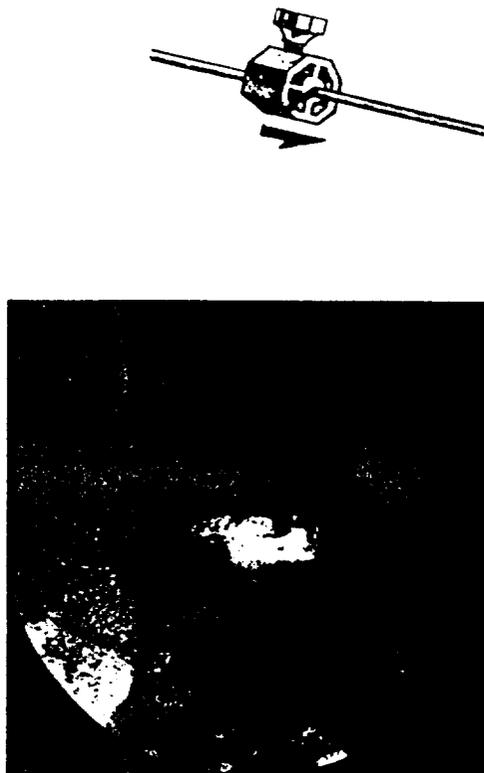


Fig. 2

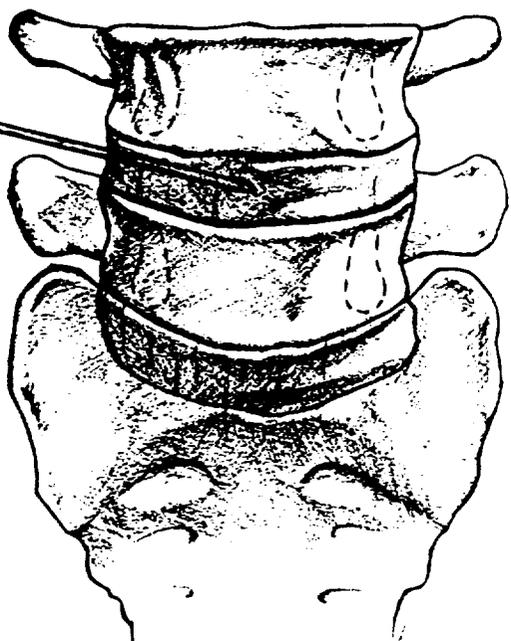


Fig. 3

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Surgical Technique at L1-L5 Levels

Straight Cannula with Dilator Insertion

Once the FlexTrocar is in the correct position within the disc, the straight cannula with tapered dilator is passed over the FlexTrocar and inserted down to the wall of the annulus. The position of the cannula is confirmed fluoroscopically in both AP and lateral views (Fig. 4).

NOTE:

Attention should be paid to monitoring the patient for radicular pain during the insertion of the cannula. If radicular pain is experienced, slight posterior angulation can be applied to the cannula to avoid contact with the anteriorly traversing nerve. Additionally, the FlexTrocar should be monitored to insure that it has not advanced during the insertion of the cannula.

Once confirmed to be in place, the tapered dilator is removed from the cannula, leaving the FlexTrocar and cannula in place. The dilator extends 2mm beyond the cannula. Therefore, when the dilator is removed from the cannula, the cannula should be advanced until it rests against the annulus. To confirm that the cannula is resting against the annulus, an oblique view is obtained (Fig. 5). The cannula stop can then be lowered to the skin level and secured in place.

The curved cannula/dilator can be used in place of the straight cannula/dilator at the L1-L5 disc levels. It is important to review the cautions (Page 21) pertaining to probe insertion prior to use of the curved cannula/dilator.

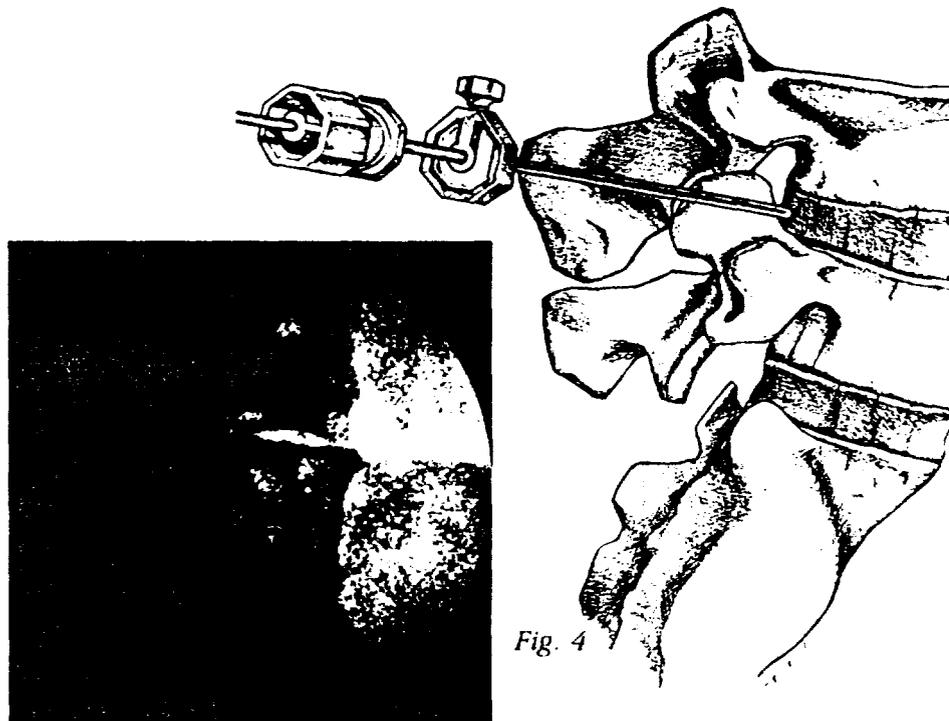


Fig. 4

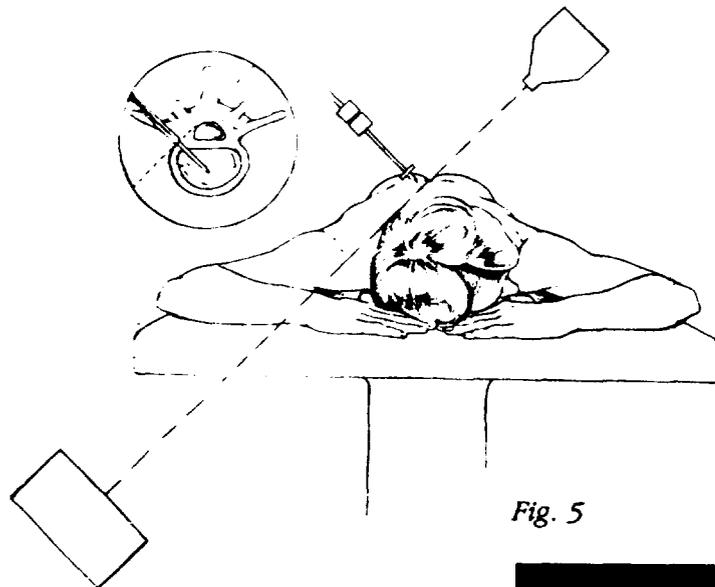
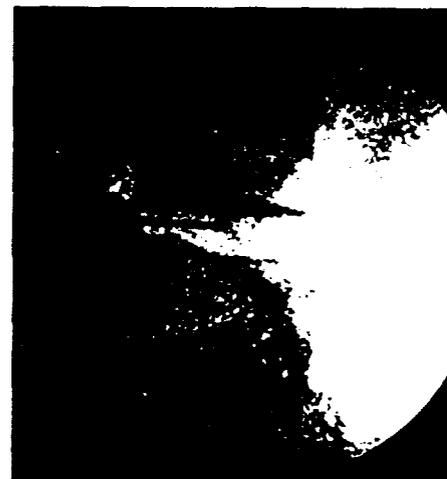


Fig. 5



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Surgical Technique at L1-L5 Levels

Incision of the Annulus

The trephine is placed over the FlexTrocar and through the cannula. The fluoroscopic unit should be perpendicular to the cannula and an oblique fluoroscopic view should be obtained, confirming that the cannula is actually against the annulus before the trephine is used. The trephine is rotated in a clock-wise motion with slight pressure to incise the annulus (Fig. 6 & 6a). After the incision has been made, the trephine and the FlexTrocar are removed from the cannula.

NOTE:
Gentle forward pressure is applied to the cannula during the removal of the trephine and the FlexTrocar to insure the position of the cannula is not displaced.

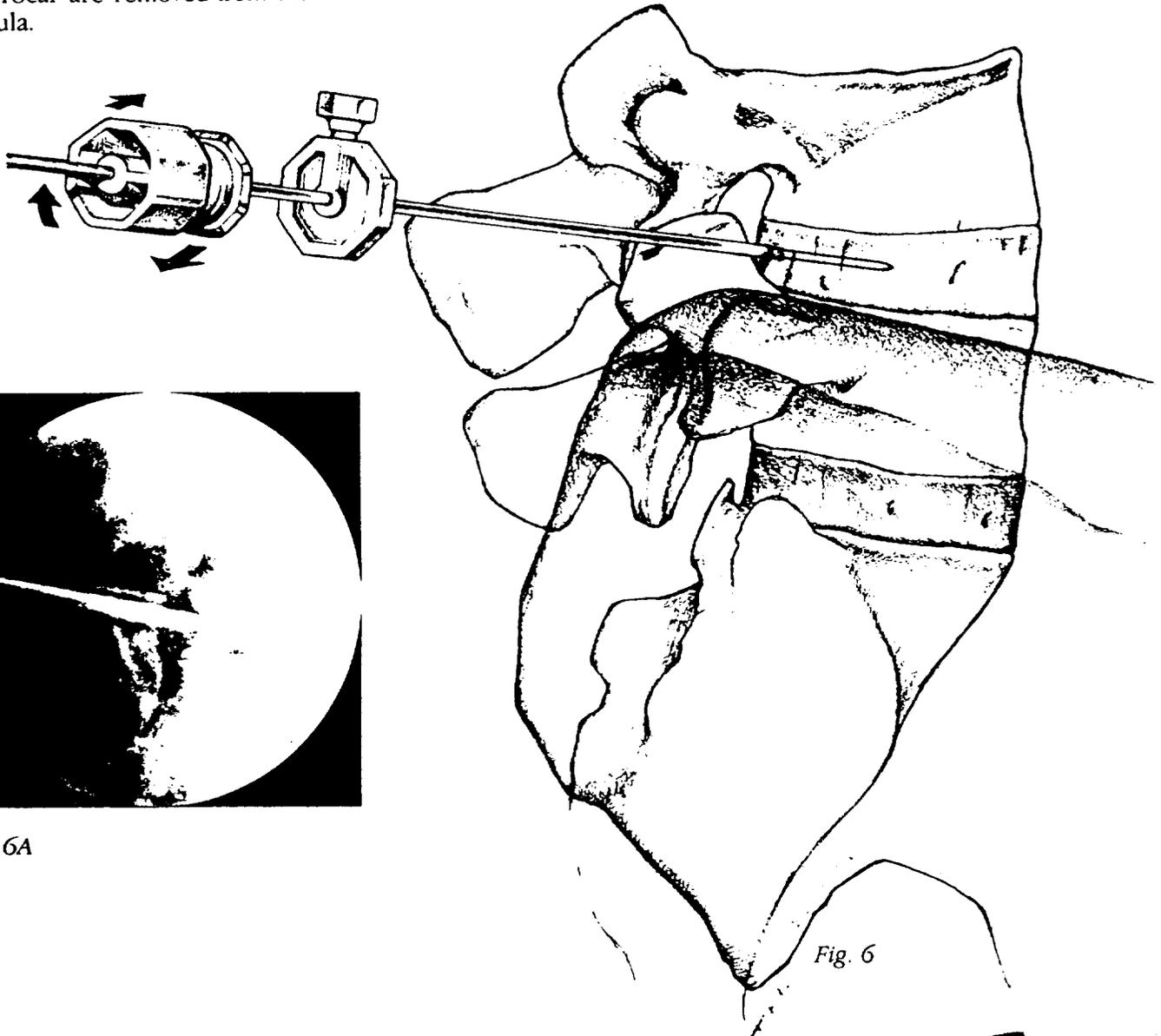


Fig. 6A

Fig. 6

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Surgical Technique at L1-L5 Levels

Insertion of the Nucleotome® Probe

The Nucleotome probe, with cannula seal nut, is inserted into the cannula and the nut is locked into place. The probe should be confirmed to be within the disc on both AP and lateral views before the footswitch is activated (Fig. 7A & 7B).

NOTE:

The position of the cannula should be checked to insure that the cannula has not been withdrawn or migrated into the disc space. Light pressure applied to the cannula stop should be maintained to insure the continued correct placement of the cannula.

When the probe is initially activated, the cutting rate of the probe (controlled by the cut rate dial on the console unit) should be at its maximum rate. By using the maximum rate, the chances of clogging the probe are minimized. Later in the case, when the flow of material has decreased, the cutting rate can be lowered to facilitate more material being extracted. Nucleus material will be resected and aspirated by the probe as it is worked back and forth within the disc space. This aspect of the procedure can be monitored by watching the nucleus material exiting the probe via the aspiration line.



Fig. 7A

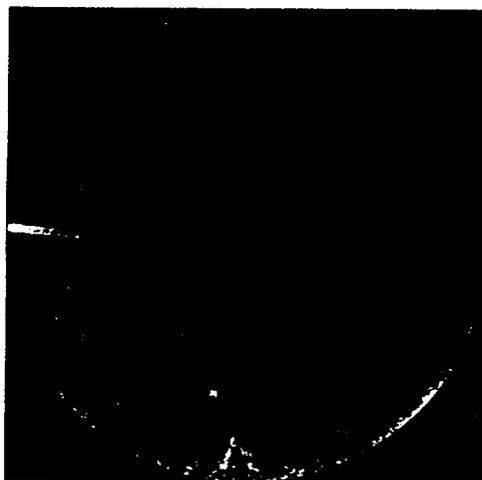
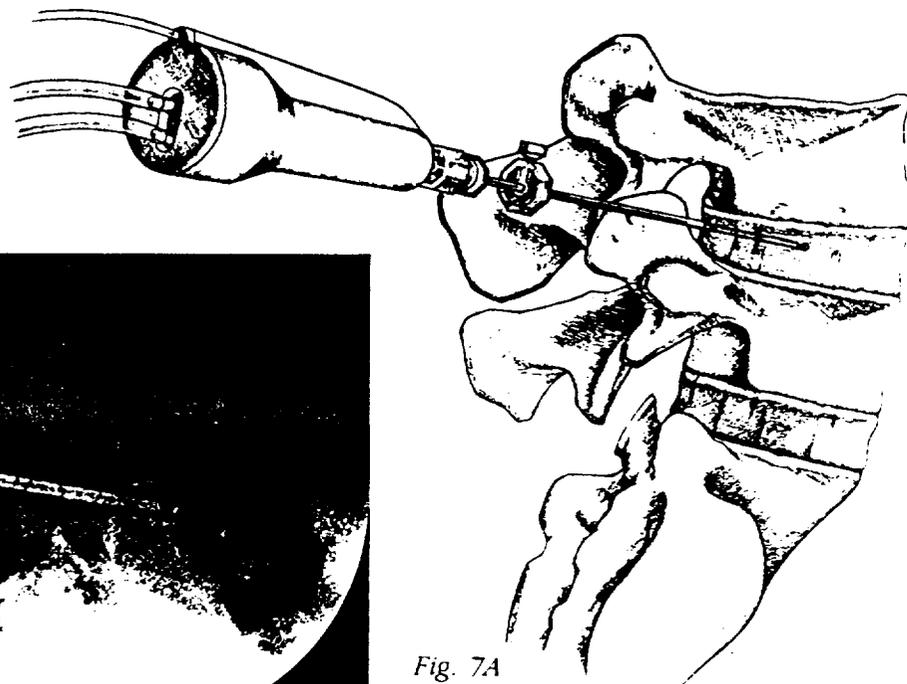


Fig. 7B

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Surgical Technique at L1-L5 Levels

The ridge on the probe handle (Fig. 8) faces the same direction as the cutting port of the probe. To insure that the maximum amount of material is removed from the area of the herniation, the cutting port should be directed toward the herniation and worked in that area until no further material can be obtained. Only then should the direction of the cutting port be rotated.

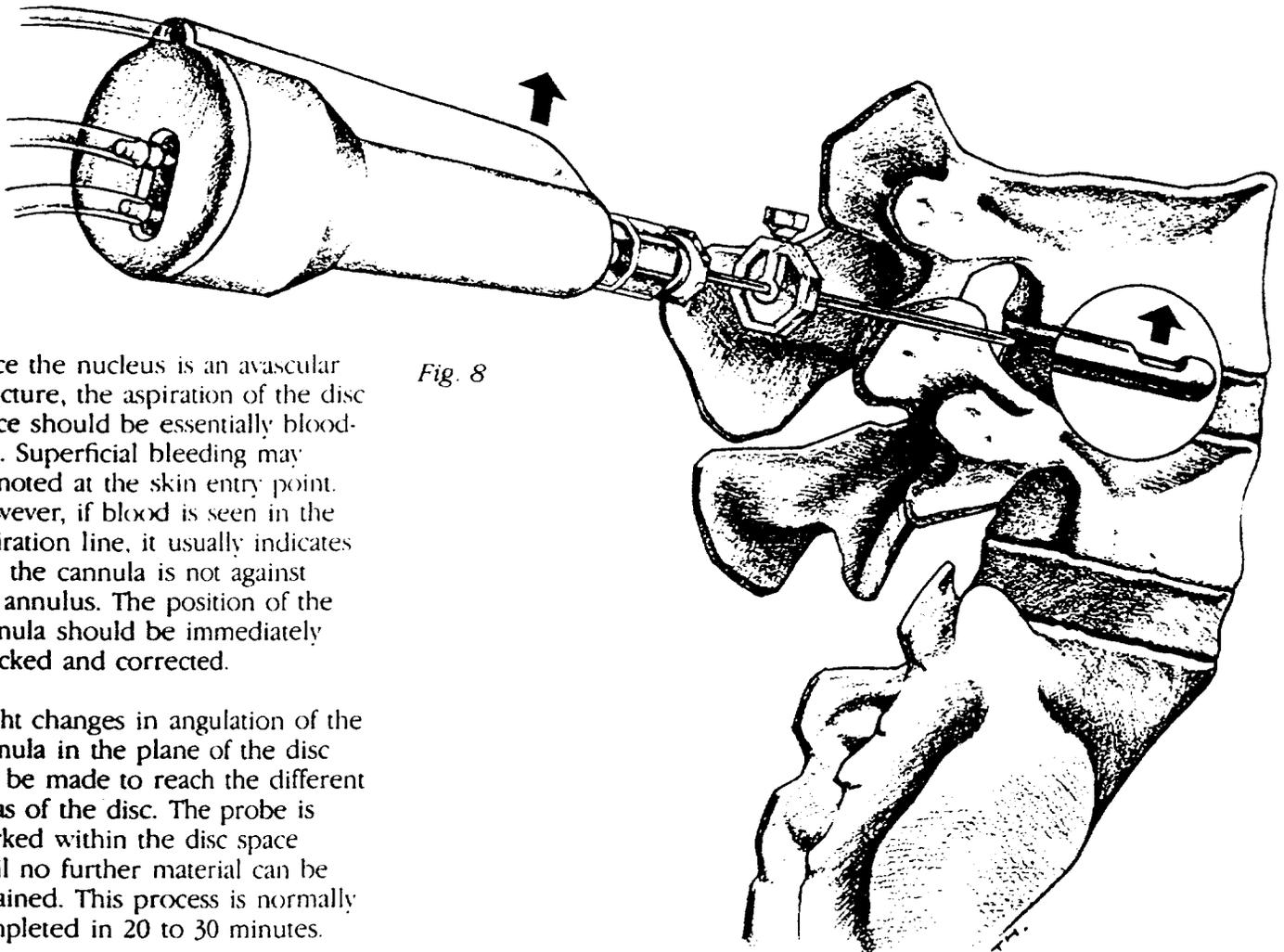


Fig. 8

Since the nucleus is an avascular structure, the aspiration of the disc space should be essentially bloodless. Superficial bleeding may be noted at the skin entry point. However, if blood is seen in the aspiration line, it usually indicates that the cannula is not against the annulus. The position of the cannula should be immediately checked and corrected.

Slight changes in angulation of the cannula in the plane of the disc can be made to reach the different areas of the disc. The probe is worked within the disc space until no further material can be obtained. This process is normally completed in 20 to 30 minutes.

Once the case is completed, the cutting action of the probe is stopped by releasing the footswitch. The probe is withdrawn completely into the cannula and both the probe and cannula are removed simultaneously.

CAUTION:

At no time should excessive force be applied to the probe handle. The probe tip can be damaged or broken if it is forced against the vertebral endplates. The initial placement of the probe should be parallel to and midway between the endplates. The probe should slide easily within the cannula. If it does not, then an obstruction is being encountered that could damage or break the probe tip.

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Surgical Technique at L5-S1 Level

Nucleotome procedure, when performed at the higher lumbar levels, usually presents a difficult approach to the center of the involved disc space. At the L5-S1 level, the straight posterolateral approach is often obstructed by the sac crest and the facets, thereby requiring an angled approach. (Fig. 9)

Key, therefore, to entry of the disc space is the selection of an entry point that is far enough medial to allow entry into the disc, and still provide a good placement of the Nucleotome instruments.

Due to the steep angle of entry that may be required, the initial orientation of the tip of the FlexTrocar against the annular wall must be adjusted to

ensure correct positioning in the center of the disc. The curved dilator with dilator is used to ensure both parallel and equidistance of the FlexTrocar to the endplates, as well as to ensure the correct positioning of the Nucleotome probe in the center of the L5-S1 disc space.

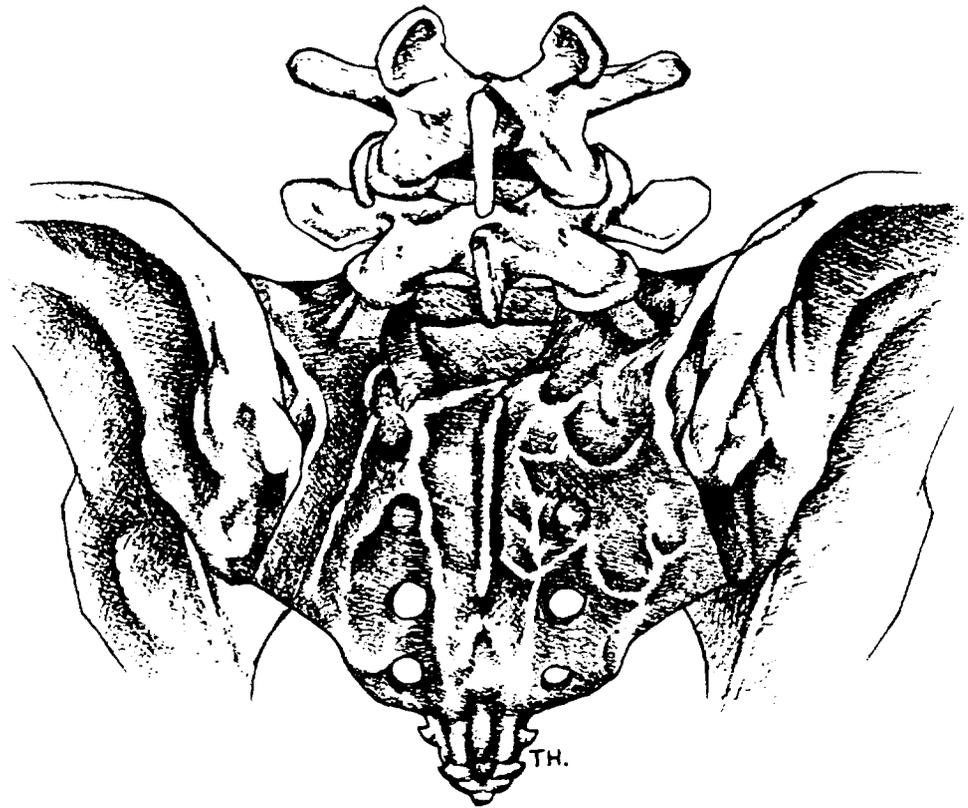


Fig. 9

Fig. 9A



Patient Positioning

The L5-S1 procedure is performed on a fluoroscopic table with the patient positioned in either the prone or lateral decubitus position. When the patient is placed in a prone position, pressure points should be cushioned and the patient flexed to decrease the lumbar lordosis and open the disc space posteriorly. If the patient is placed in the lateral decubitus position, in addition to making sure that the patient is flexed, care must be taken to prevent rotation of the shoulders and hips during the procedure. Such rotation can cause misinterpretation of the actual instrument placement when viewed in the AP view. When the patient is positioned correctly, in the AP view the spinous process is midway between the pedicles (Fig. 9A). If the patient is incorrectly positioned, the patient should be rotated into the correct position and secured.

Surgical Technique at L5-S1 Level

FlexTrocar™ Placement

A 4mm skin incision is made at the entry point and the FlexTrocar is inserted on the side of the herniation.

The trajectory of the FlexTrocar should be directed to the center of the L5-S1 disc space. As the FlexTrocar is advanced, it is monitored in the lateral fluoroscopic view. As the tip of the FlexTrocar contacts the posterior vertebral body line and the "gritty" sensation of the annulus is felt, an AP view is obtained. The AP view is used to confirm that the tip of the FlexTrocar is lateral to a line that connects the medial border of the pedicles (*Fig. 12A & 12B*). Since the thecal sac lies medial to this line, if the tip of the FlexTrocar is lateral to the line and is touching the annulus, the FlexTrocar will not traverse the thecal sac. As with the procedure at the higher lumbar levels, the patient is continually monitored for radicular pain.

NOTE:

The tip of the FlexTrocar should not be anterior to the posterior vertebral body line when the annulus is felt. This prevents injury to the iliac vessels that have bifurcated and lie posterolaterally at the L5-S1 level.

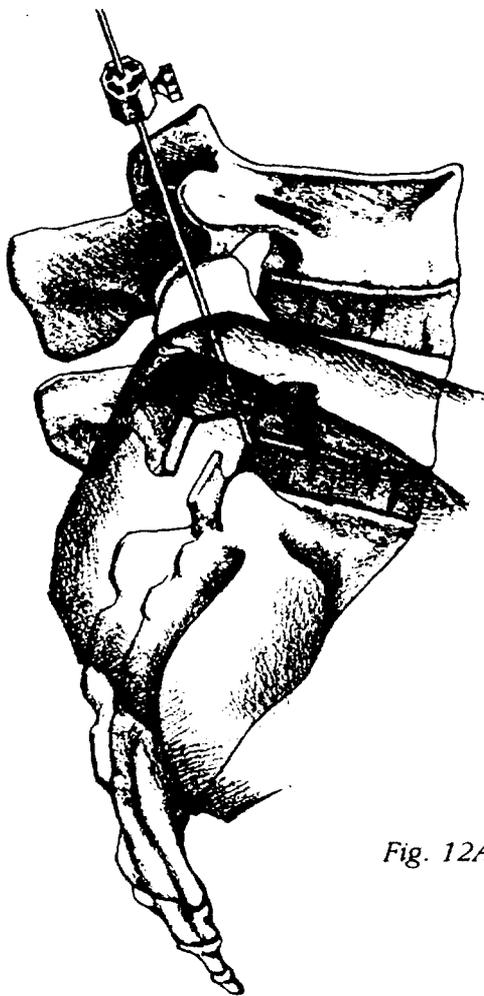


Fig. 12A

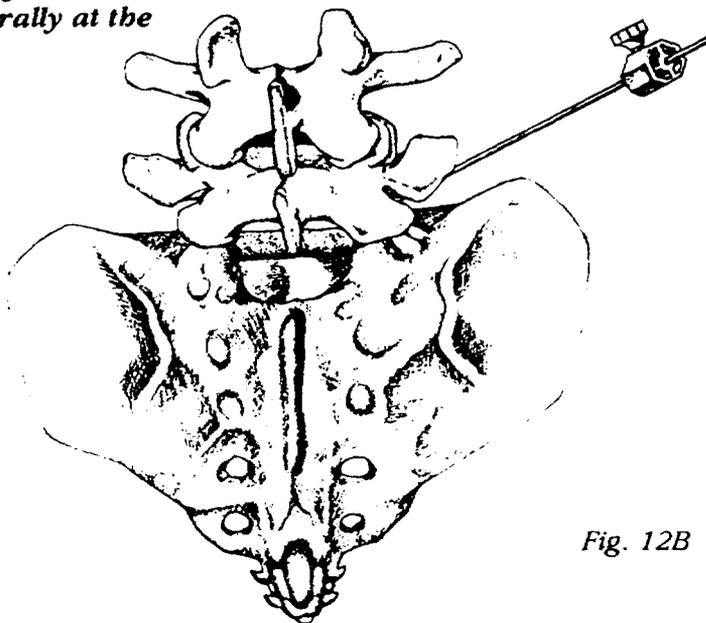


Fig. 12B

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Surgical Technique at L5-S1 Level

Curved Cannula with Dilator Insertion

Due to the angle of approach to the disc space, it can be difficult to achieve a parallel placement using the straight cannula/dilator. The curved cannula has been designed to accomplish this parallel placement.

The Y-shaped guide on the curved cannula is used to control the rotation and angulation of the instrument (Fig. 13). It also serves as a reference point for determining the proper orientation of the curve during insertion. The cannula curves away from the "Y" guide.

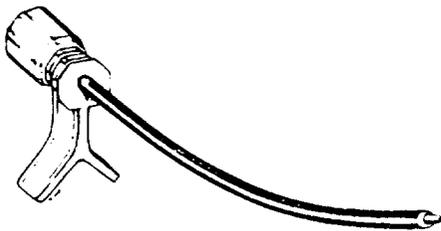


Fig. 13

Once the tip of the FlexTrocar has been placed at the wall of the annulus and confirmed in an AP view not to be traversing the thecal sac, the curved cannula with dilator is passed over the FlexTrocar and advanced to the wall of the annulus (Fig. 14A & 14B). Friction is caused by passing the curved cannula/dilator over the straight FlexTrocar and by inserting and removing the trephine. Unless the FlexTrocar is securely held and controlled, it may advance or withdraw from its position. The position of the FlexTrocar should be checked fluoroscopically.

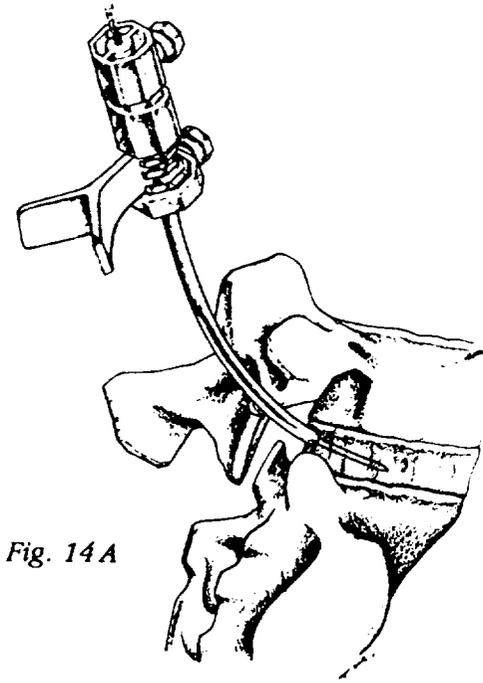


Fig. 14A

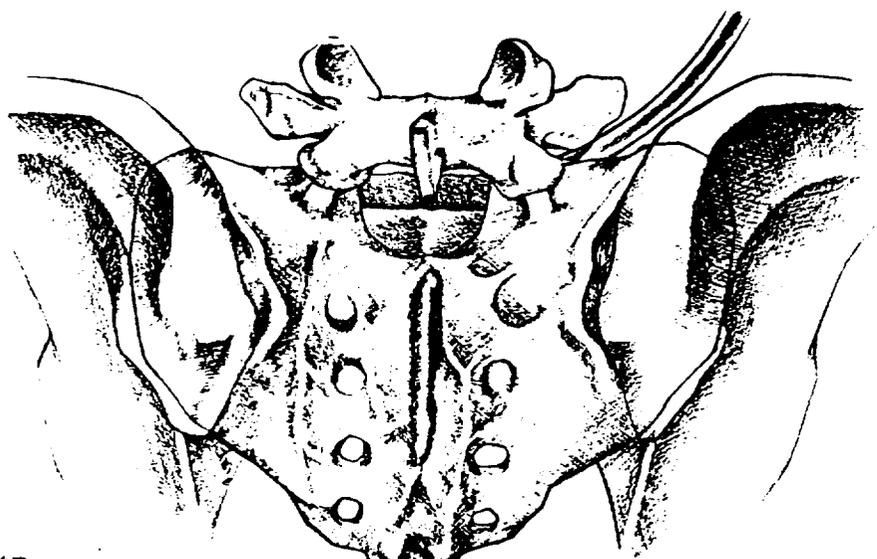
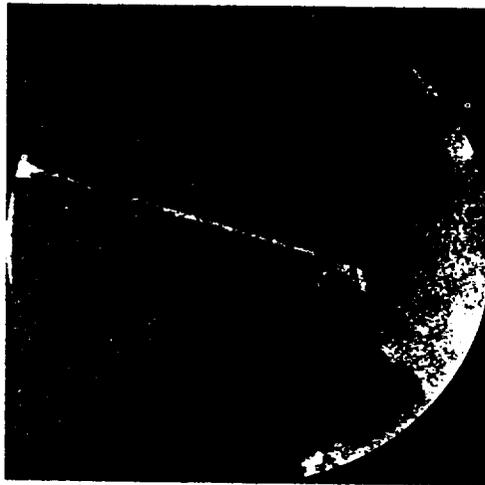


Fig. 14B

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Surgical Technique at L5-S1 Level

NOTE:

Due to the rigidity of the lumbar fascia, it may be difficult to dilate it with the curved cannula. To facilitate placement, the straight cannula with dilator can first be passed over the FlexTrocar to the lumbar fascia. Once the straight cannula has been advanced past the fascia, it is removed and the curved cannula with dilator can then be used.

NOTE:

Attention should be paid to monitoring the patient for radicular pain during the insertion of the cannula. If radicular pain is experienced, slight posterior angulation can be applied to the cannula to avoid contact with the anteriorly traversing nerve. Additionally, the FlexTrocar should be monitored to insure that it has not advanced during the insertion of the cannula.

To achieve both parallel and equidistant placement of the FlexTrocar in the plane of the disc, the curved cannula with dilator is held firmly against the annular wall and the FlexTrocar is withdrawn just within the cannula. The curved cannula can then be rotated to obtain the correct entry point into the disc. Once the curved cannula has been rotated, the FlexTrocar is advanced to the center of the disc and confirmed to be in the correct position in both AP and lateral views (Fig. 15 & 16).

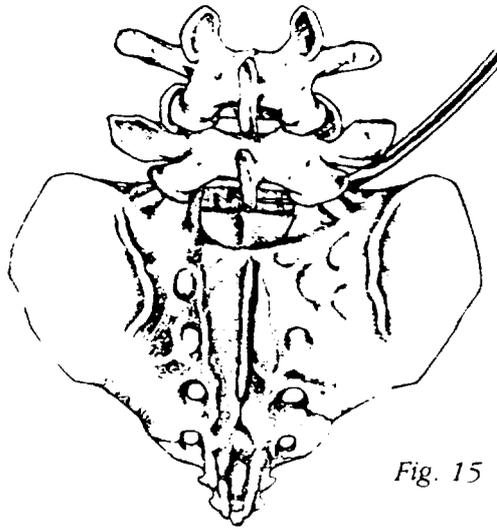


Fig. 15

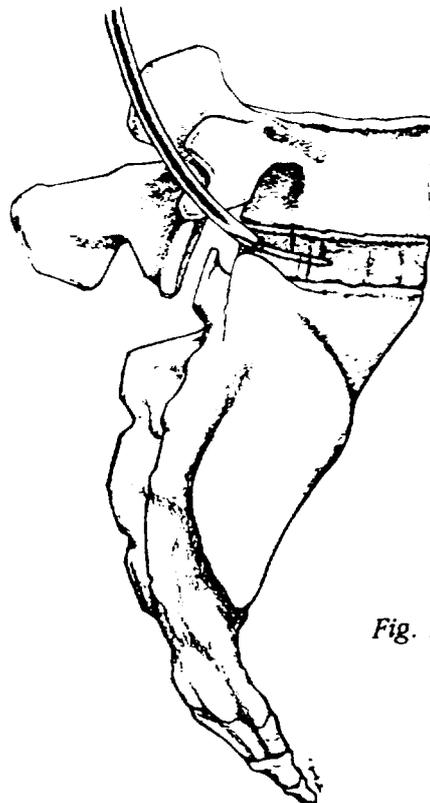
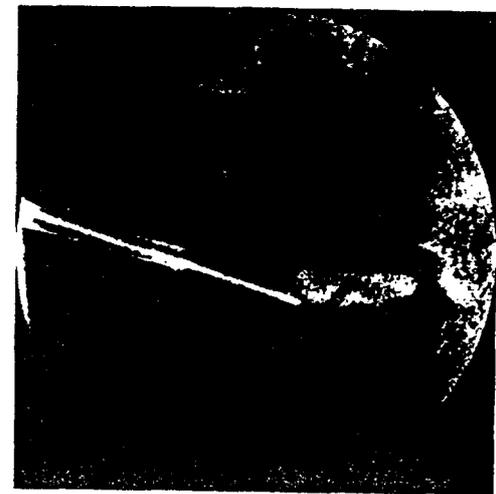


Fig. 16



Once confirmed to be in place, the tapered dilator is removed from the cannula, leaving the FlexTrocar and cannula in place. The dilator extends 2mm beyond the cannula. Therefore, when the dilator is removed from the cannula, the cannula should be advanced until it rests against the annulus. An oblique fluoroscopic view is obtained to confirm that the curved cannula is against the annular wall. It is important to monitor the FlexTrocar to insure that it has not advanced. The cannula stop can then be lowered to the skin level and secured in place.

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Surgical Technique at L5-S1 Level

Incision of the Annulus

The trephine is placed over the FlexTrocar and through the cannula. The fluoroscopic unit should be perpendicular to the cannula and an oblique fluoroscopic view should be obtained, confirming that the cannula is actually against the annulus before the trephine is used. The trephine is rotated in a clockwise motion with slight pressure to incise the annulus (Fig. 17 & 17A). After the incision has been made, the trephine is removed from the cannula.

The FlexTrocar should not be removed from the curved cannula until the Nucleotome Probe has been readied for insertion into the disc space. At that time, the curved cannula is held firmly in place while the FlexTrocar is removed from the curved cannula and the Nucleotome probe inserted.

NOTE:

Special attention must be paid to keeping forward pressure on the cannula, or the cannula may be displaced when the FlexTrocar and trephine are being removed. If this occurs, the FlexTrocar and trephine are reinserted and after the correct position has been confirmed, the annulus is again incised.

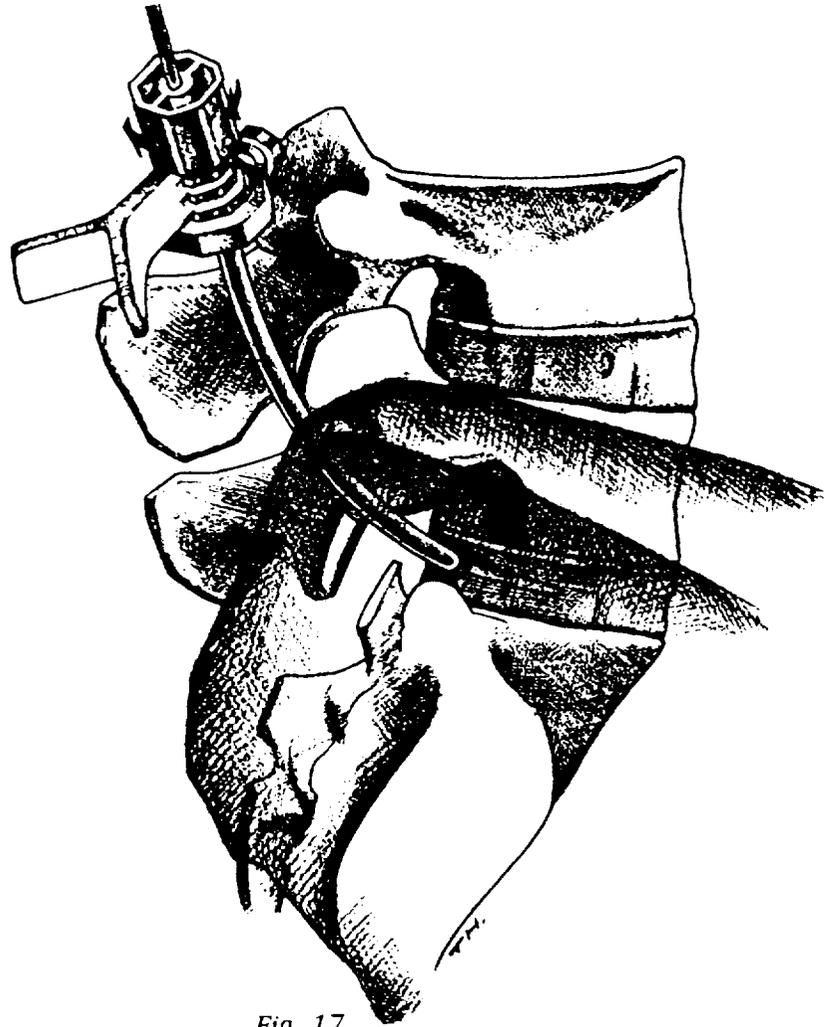


Fig. 17



Fig. 17A

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Surgical Technique at L5-S1 Level

Insertion of the Nucleotome® Probe

The Nucleotome probe, with cannula seal nut in place, is inserted into the curved cannula and the seal nut is locked into place. The probe should be confirmed to be within the disc on both AP and lateral views before the footswitch is activated (Fig. 18).

NOTE:

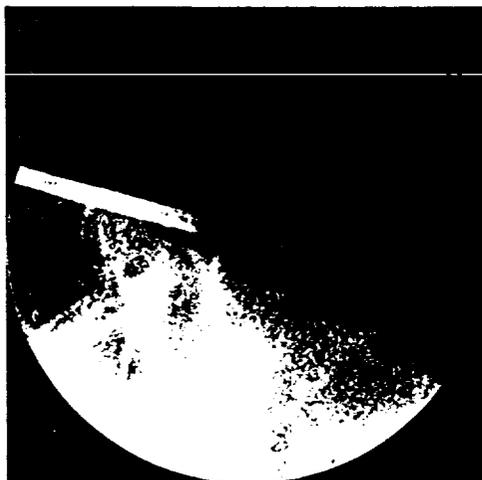
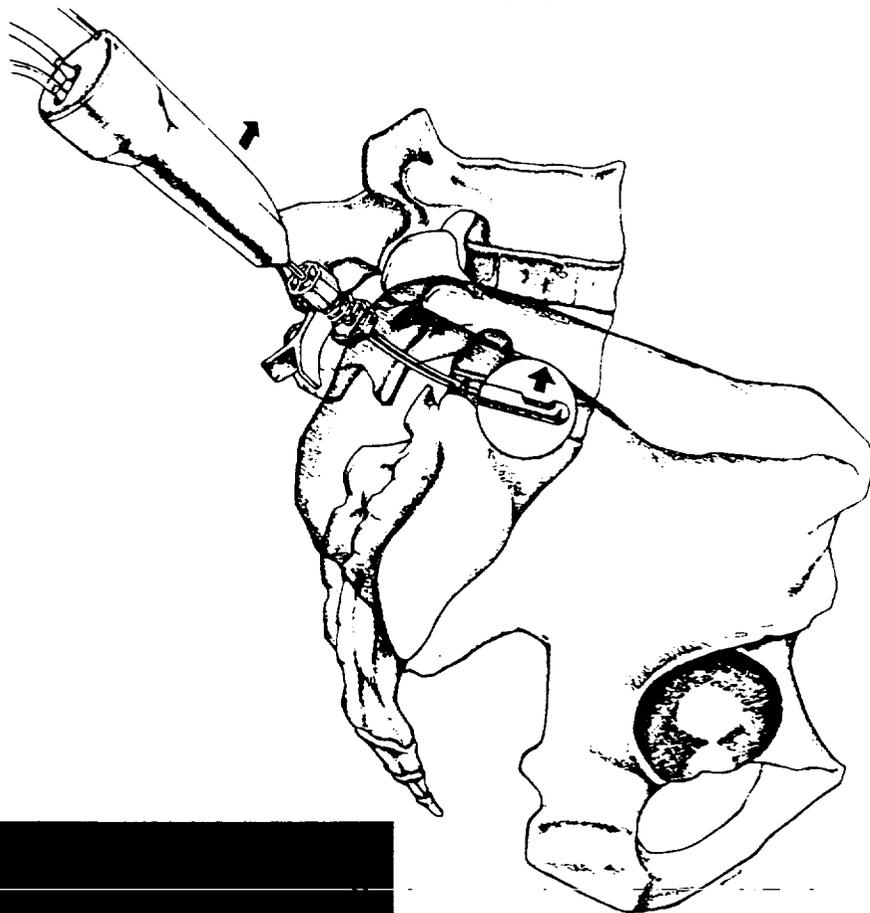
The position of the cannula should be checked to insure that the cannula has not been withdrawn or migrated into the disc space. Light pressure applied to the cannula stop should be maintained to insure the continued correct placement of the cannula.

When the probe is initially activated, the cutting rate of the probe (controlled by the cut rate dial on the console unit) should be at its maximum rate. By using the maximum rate, the chances of clogging the probe are minimized. Later in the case, when the flow of material has decreased, the cutting rate can be lowered to facilitate more material being extracted. Nucleus material will be resected and aspirated by the probe as it is worked back and forth within the disc space. This aspect of the procedure can be monitored by watching the nucleus material exiting the probe via the aspiration line.

The ridge on the probe handle (Fig. 18) faces the same direction as the cutting port of the probe. To insure that the maximum amount of material is removed from the area of the herniation, the cutting port should be directed toward the herniation and worked in that area until no further material can be obtained. Only then should the direction of the cutting port be rotated.

NOTE:

The curved cannula is lined with Teflon® to reduce the friction caused during the insertion of the probe and the introduction of the instruments. If, during the procedure, the probe is withdrawn from the curved cannula, the cutting port, as indicated by the ridge on the probe handle, should face inward in the same direction as the curve. This will prevent the cutting port from damaging the liner.



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Fig. 18

(5)

Surgical Technique at L5-S1 Level

Rotation of the curved cannula, in the plane of the disc, can be made to reach the different areas of the disc. The probe is worked within the disc space until no further material can be obtained. This process is normally completed in 20 to 30 minutes.

Once the case is completed, the cutting action of the probe is stopped by releasing the foot-switch. The probe is withdrawn completely into the cannula and both the probe and cannula are removed simultaneously.

CAUTION:

At no time should excessive force be applied to the probe handle. The probe tip can be damaged or broken if it is forced against the vertebral endplates. The initial placement of the probe should be parallel to and midway between the endplates. The probe should slide easily within the cannula. If it does not, then an obstruction is being encountered that could damage or break the probe tip.

Skin Closure

A sterile bandage is placed over the operative site. Sutures are not normally required (Fig. 19).

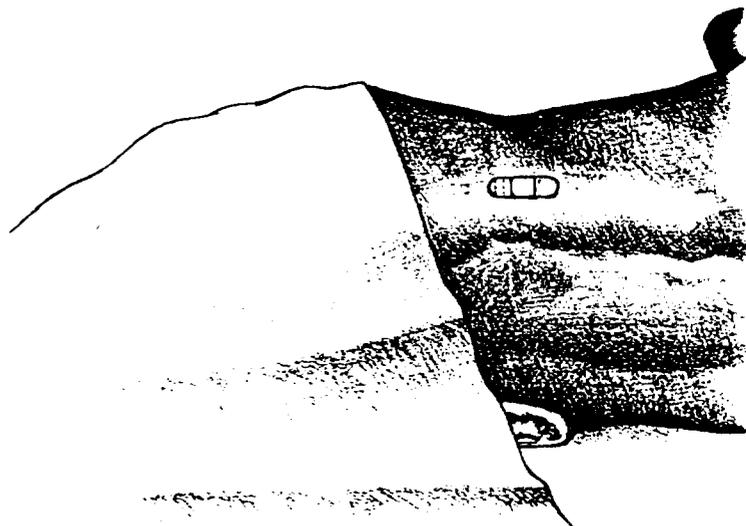


Fig. 19

Immediate Postoperative Program

The postoperative program normally follows that of a microdiscectomy procedure. The patient should be advised that he has undergone a surgical procedure and should restrict activity. A conservative postoperative rehabilitation program would include trunk stabilization and strengthening exercises as the patient tolerates. Relaxation of restrictions should be determined by the progress of the patient.

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(10)

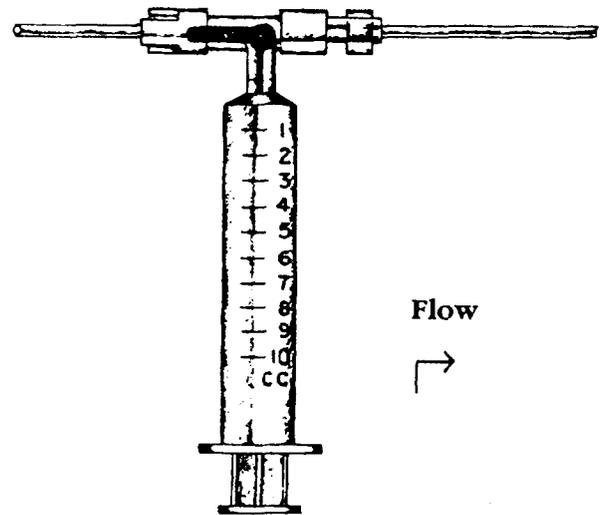
Removal of Clog from Probe and Tubing

Although not occurring frequently, the probe can become clogged with nucleus material. In the event that clogging occurs, as evidenced by the lack of movement of the nucleus material in the direction of the aspiration bottle, **the probe is deactivated, the seal nut on the cannula is unlocked and the probe is completely withdrawn from the patient.** The FlexTrocac is reinserted through the cannula to maintain the position of the cannula with the annular incision.

A 10cc syringe of sterile solution is attached to the three-way stopcock. The stopcock handle is turned in the direction of the aspiration bottle and the plunger of the syringe is depressed, clearing any clogging in the direction of the probe.

To clear a clog in the direction of the aspiration bottle, the console is first placed in the "LOAD" mode. The stopcock handle is rotated in the direction of the probe. The syringe is depressed, thereby clearing any clog in the direction of the aspiration bottle (Fig. 20). The console is placed in the "RUN" mode and the stopcock handle is rotated in the direction of the syringe. The probe can then be reinserted and the case continued.

To Collection
Bottle



To Probe



Flow



Fig. 20

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Attachment F: SURGICAL PROCEDURE LITERATURE

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Percutaneous Lumbar Discectomy

Review of 100 Patients and Current Practice

PARVIZ KAMBIN, M.D.,* AND JONATHAN L. SCHAFFER, M.D.**

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Percutaneous Lumbar Discectomy

Review of 100 Patients and Current Practice

PARVIZ KAMBIN, M.D.* AND JONATHAN L. SCHAFFER, M.D.**

In a prospective study, 100 patients with 102 herniations of the nucleus pulposus at L2-L3, L3-L4, L4-L5, and L5-S1 and unremitting radicular pain were treated by percutaneous lumbar discectomy. Ninety-three patients were available for follow-up examination. Three patients had died, and four patients could not be located for this review, but all had been followed for more than one year postoperatively and were judged to have had an excellent result at the time of the last follow-up examination. Fifty-nine patients have been followed for longer than two years postoperatively, with a maximum follow-up period of six years. Evaluations were based on modified MacNab criteria and patient interview, questionnaire, and examination. Eighty-one patients (87%) were judged to be successes, since they were pain-free and had returned to gainful employment and their preinjury activity levels. Twelve patients' operations (13%) were judged to be failures and required repeat surgical procedures at the level of the presenting pathologic condition. Three patients (not included in the follow-up group) died of unrelated causes; they had been followed for a minimum of 15 months postoperatively and were previously judged to have had an excellent result. No major complications, including superficial or deep infections, discitis, or neurovascular compromise, were encountered. Meticulous selection of patients for percutaneous lumbar discectomy is the key to success with the method.

lumbar discectomy is the key to success with the method.

Lumbar disc herniation remains a major national health problem. It has been estimated that up to 80% of the population experiences low-back pain at some time during their lives.^{7,13} The percutaneous posterolateral approach to the lumbar intervertebral disc represents an alternative method for the treatment of lumbar disc protrusion and its associated radiculopathy.

The majority of patients with radicular pain secondary to disc protrusion do respond to conservative management. When surgical intervention becomes necessary, the patient and surgeon have three alternatives from which to choose: laminectomy and discectomy, chemonucleolysis, and percutaneous posterolateral discectomy. One ideally desires removal of all pathologic material while sparing the integrity of the normal anatomy. Laminectomy, however, permits direct visualization of the nerve roots and the compressing elements and, thus, continues to represent an effective and reliable method for the treatment of lumbar radiculopathy due to a protruded intervertebral disc.

The concept of decompression of the nucleus, rather than direct visualization and excision of the protruded part of the disc, is not new. In 1951, Hult reported the relief of both low-back and sciatic pain in 30 patients following fenestration of the annulus through an open retroperitoneal approach, stating, "If an anterolateral incision is made in the disc, it should be possible to divert the pressure in

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that direction and thereby prevent it from being transmitted posteriorly."⁸ Stern and Smith, in an *in vitro* study, demonstrated that the decrease in intradiscal pressure following the injection of chymopapain is due to the digestion of proteoglycan core proteins from the nucleus.²⁰ The failure of chemonucleolysis is, in part, due to the inability of the enzyme to digest the collagenized nuclear fragments. In the course of percutaneous lumbar discectomy, the collagenized nuclear fragments are evacuated by mechanical means. In addition, percutaneous discectomy is less destructive than laminectomy in the surgical management of dorsolateral nuclear protrusion. The percutaneous approach permits the decompression and evacuation of the bulge of the herniation without entrance into the spinal canal and without destruction of the facets and the articular processes.

Percutaneous discectomy has been reported in the literature as a safe and effective procedure. The percutaneous posterolateral approach for vertebral body biopsy was first described by Craig.² Since Mixter and Barr's classic description of the association of a herniated nucleus pulposus with sciatica¹⁵ and treatment of this condition by laminectomy, surgeons have desired a more precise and less destructive surgical approach. Kambin and Gellman¹⁰ reported the combination of conventional lumbar laminectomy with percutaneous dorsolateral decompression of the intervertebral disc as early as 1973. Hijikata,⁶ Kambin *et al.*,⁹⁻¹² Friedman,⁴ Hausmann and Forst,⁵ Onik *et al.*,¹⁷ Schreiber and Suezawa,¹⁸ Suezawa and Jacob,²¹ Monteiro,¹⁶ and Shepperd¹⁹ have all reported favorable results following percutaneous discectomy. The advantages of percutaneous discectomy include avoidance of epidural bleeding and perineural fibrosis, elimination of reherniation in the spinal canal through the surgically induced annular fenestration, preservation of spinal stability, and establishment of a portal away from the neural elements for future herniation.⁹⁻² In addition,

future surgical procedures are not compromised, and the hospitalization is more cost effective than traditional approaches, since the operating room and hospitalization times are decreased.¹¹

Results of a prospective study of 100 consecutive patients who have been treated with percutaneous lumbar discectomy are reported here. Fifty-nine of these patients have been followed for a minimum of two years. Modified MacNab criteria¹⁴ were utilized to evaluate the results of the surgical procedure. The surgical technique is updated from previous reports and specific recommendations are made to ensure a successful result.

MATERIAL AND METHODS

The patient selection criteria and operative technique for percutaneous lumbar discectomy have been described in detail⁹⁻¹² and will be briefly reviewed and updated. All patients presenting to the first author were eligible for the procedure, if they met the following criteria: (1) unremitting, persistent radiculopathy at L3-L4, L4-L5, or L5-S1; (2) failure of appropriate conservative therapy; (3) neurologic impairment as reflected by sensory deficits, reflex abnormalities, and motor weakness; (4) correlative electromyography in the absence of correlative neurological deficits; (5) positive tension signs; and (6) correlative imaging studies.

The inciting episode, work history, general medical health, psychosocial environment, and description of the patient's symptoms were recorded on a standard report form. The physical examination findings, any changes noted at each visit, and the results of the diagnostic studies were duly recorded. Extreme care was taken to exclude patients with a sequestered disc herniation, bony lateral recess stenosis, spinal stenosis, and/or pedicle-induced nerve-root kinking. Patients with developmental anomalies or tumors and those patients with reherniation following laminectomy or chemonucleolysis were not candidates for this procedure because of the potential for anatomic distortion. All patients had plain roentgenographic examinations of the lumbar spine. The vast majority of the patients (92 of 100) had metrizamide lumbar myelographies followed by computerized tomographic (CT) scans when necessary. The remaining eight patients were allergic to iodinated compounds and did not have myelographies. For these remaining patients, correlative electromyography and CT scans were obtained. Since 1985, the authors have added magnetic resonance imaging

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(MRI) in these situations. All patients signed a written consent form that included a statement that the patient understood that if the percutaneous lumbar discectomy failed, then a lumbar laminectomy would be necessary. Prior to surgery, all patients were evaluated by comprehensive medical history, physical examination, and routine laboratory studies.

Postoperative examinations were made at one, two, and four weeks, then at three, six, and 12 months, followed by annual examinations. The follow-up examination consisted of chart review, physical examination, and patient interviews. All patients were again contacted specifically for this review, and the majority have recently been examined by one of the present authors. A six-part questionnaire was filled out by all patients contacted and included detailed questions about activity level, work history, back pain, and pain relief postoperatively. Specifically, the patients were queried about the results of the surgery and if they felt "cured," "helped, but not cured," or "about the same." Data were recorded using standard computer programming on a microcomputer for compilation and analysis, and the surgical results were analyzed using modified MacNab criteria for function levels.

In addition to the previously described operative technique,⁹⁻¹¹ the technical details discussed below are to be considered in light of experience with the 100 patients presented in this study. Percutaneous lumbar discectomy is an operative procedure invading the tissues of the spine and, as such, requires meticulous sterile technique. The morbidity associated with vertebral body osteomyelitis and disc space infections dictates that prophylactic antibiotics be used and that the procedure be performed in the appropriate surgical environment. All of the patients in the study received prophylactic preoperative antibiotics.

The skin preparation and surgical draping procedures are identical to those of an open spine procedure. Blockage of rotation of the C arm by the sterile sheets or drapes is not uncommon, and extreme care must be taken to avoid blocking rotation of the C arm X-ray unit. Full rotation of the C arm will assure easily reproducible anteroposterior and lateral imaging.

The patient is placed in the prone position on a radiolucent operative table with a well-padded radiolucent frame extending from the ilium to the side of the chest wall. When discectomy at the L5-S1 disc space is performed, the lumbosacral spine should be kept flat or in flexion. Slight traction utilizing the weight of the lower extremities on a flexed table may be helpful in achieving adequate evaluation of the L5-S1 disc space.

A 1% Xylocaine (Astra, Westboro, Massachusetts) solution is used as a local anesthetic, and proper anesthetic monitoring is provided by the anesthesiologist. If necessary, to relax the patient and ensure patient comfort, small amounts of short-acting narcotic agents are administered by the anesthesiologist. However, no patient is narcotized excessively, as intraoperative communication between the surgeon and patient is vital. The skin, subcutaneous tissue, fascia, and muscle layers are infiltrated with the local anesthetic. Extreme caution is exercised to avoid periannular infiltration of the local anesthetic, since infiltration of the deep muscle layer and periannular area will anesthetize the nerve root and predispose it to injury.

Correct positioning of the 18-gauge needle is crucial to the success of the percutaneous discectomy procedure and must be performed with roentgenographic assistance (Fig. 1). The point of entry is 10-12 cm from the midline. A preoperative abdominal CT scan through the appropriate disc level is helpful in determining the point and angle of entry, thus avoiding inadvertent peritoneal puncture. When the instruments are introduced too close to the midline, they bypass the nucleus, and a far lateral approach greatly enhances the risk of bowel rupture and violation of the peritoneal cavity (see Fig. 1). Ideally, needle placement should be directed parallel to the vertebral end plates at an angle of 35° to 45°, thus entering the annulus at the 11 or 1 o'clock position in reference to the spinal processes as seen on the lateral roentgenographic projection. On the anteroposterior (AP) projection, the tip of the needle should be immediately lateral to the superior articular process of the inferior vertebra or in alignment with the midportion of the pedicle.

As the needle is inserted, the surgeon must rely on hand-eye coordination. Resistance should be encountered when the needle reaches the annulus. If no resistance is encountered and the lateral roentgenographic projection demonstrates that the needle has bypassed the annulus, a vertical insertion has been performed (Fig. 2). An AP roentgenogram would confirm that the needle has not reached the annulus. Withdrawal of the needle and reinsertion at an angle closer to the horizontal is indicated. In contrast, if the needle has been inserted at an excessively horizontal angle, which would usually cause some resistance, the lateral roentgenogram would demonstrate that the tip of the needle has not reached the annulus (Fig. 3). Withdrawal of the needle and reinsertion at a more vertical angle are required.

Following proper positioning of the needle, the stylet of the needle is withdrawn and replaced by a

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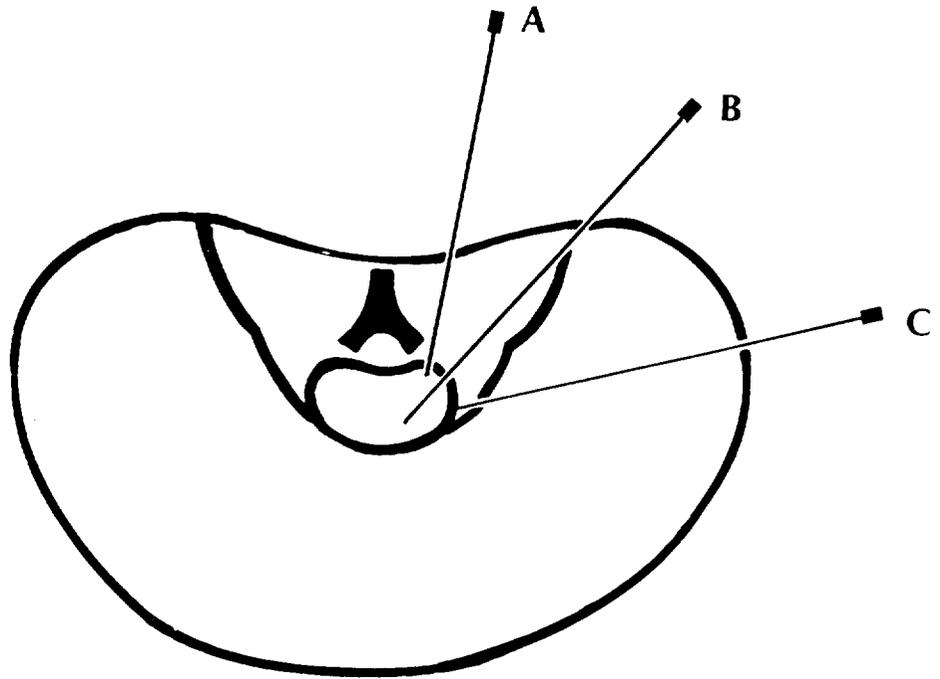


FIG. 1. (A) The correct positioning of the needle. (B) and (C) Improper introduction of the needle.

fine (0.028-inch) Kirschner wire. As the guide wire engages the annulus, the surgeon should experience resistance to further penetration. Care must be taken to ensure that the guide wire does not overpenetrate the annular fibers; ideally, a depth of approximately 2 mm is adequate. The needle is then withdrawn over the guide wire, and the cannulated trocar is inserted in the exact direction of the guide wire. The guide wire should be fully

withdrawn prior to full insertion of the cannulated trocar to lessen the chance of nerve entrapment. The trocar should be stabilized and held firmly against the annulus. Angulation of the trocar during insertion will cause friction, migration, and pain and should be avoided. Positioning is con-

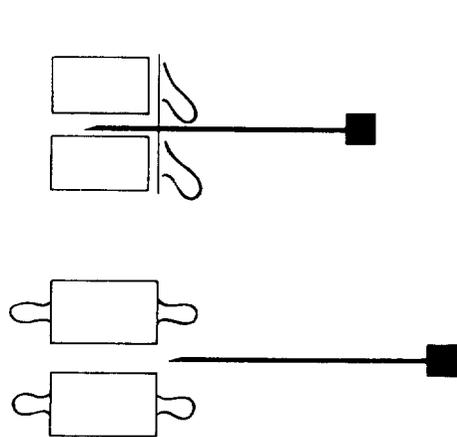


FIG. 2. Incorrect vertical insertion of the needle.

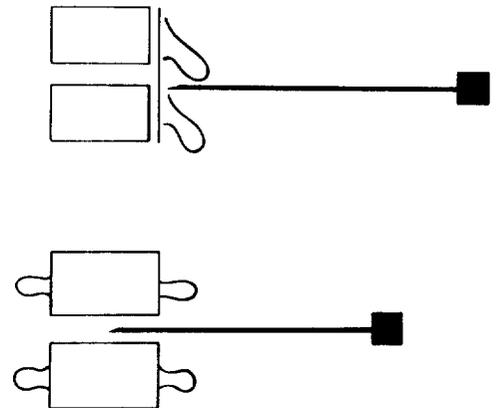
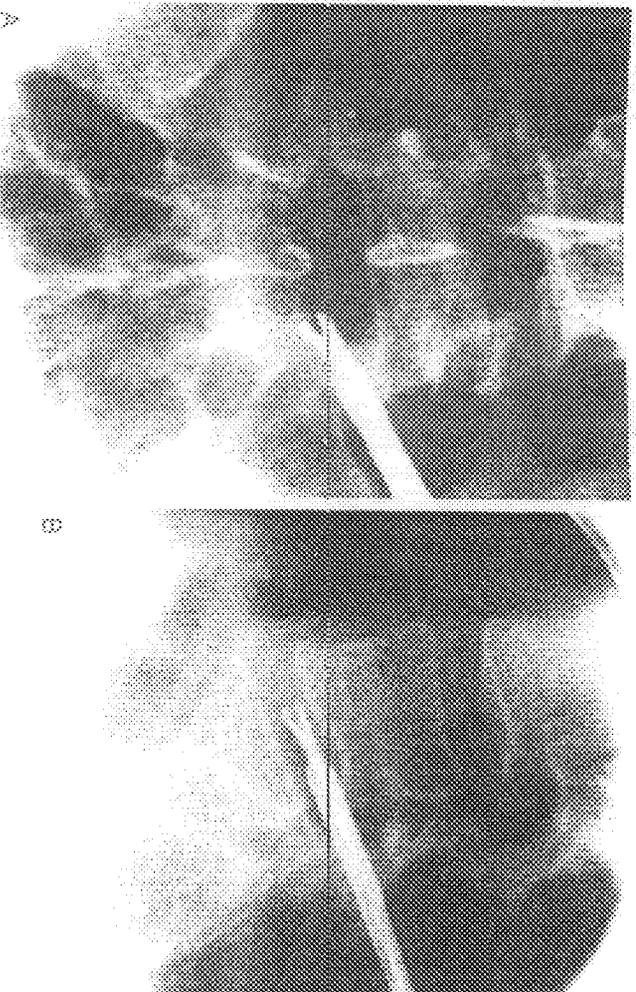


FIG. 3. Incorrect horizontal insertion of the needle.

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FIGS 4A AND 4B. (A) Anteroposterior intraoperative study showing the forceps at the L5-S1 disc space. (B) Lateral intraoperative study showing the forceps at the L5-S1 disc space.

stannily checked roentgenographically at each step of the procedure.

The sheath, with an internal diameter of 4.9 mm, is passed over the trocar until it reaches the annulus fibrosus. A spinal needle is then inserted around the inner diameter of the sheath, penetrating the annulus. This simple step should not produce radicular pain; thus providing assistance in the detection of nerve root entrapment. If the nerve is entrapped, introduction of the needle will cause severe radicular symptoms, and repositioning of the instrument is required. Penetration of the annulus by the needle also permits the centering of the sheath over the annulus prior to the introduction of the cutting instrument.

The sheath is engaged to the annulus fibers by firm and constant rotary movement. The sheath is held tightly in the surgeon's hand to prevent axial or perpendicular migration. The instrument design permits only 2 cm of instrument penetration beyond the tip of the sheath. Central navigation of the sheath would permit deeper introduction of the instrument, potentially causing vascular or bowel injuries. The position of the sheath is roentgenographically monitored at each step.

Annular fenestration is accomplished with a series of increasingly larger cutting instruments. Sufficient fenestration of the annulus is essential. Although the instrument design does not permit

excessive penetration into the disc space, the depth of the instruments should be monitored roentgenographically. Adequate evacuation of the nuclear material is necessary to provide decompression of the intervertebral disc. A combination of the deflector tube and flexible forceps, angled forceps, back biting forceps, and funnel suction with a 50-ml syringe is utilized to evacuate the posterior fragments. Most of the fragments are reached in the areas just adjacent to the open end of the sheath, rather than the center of the disc space. During evacuation of the L5-S1 disc space, the use of flexible forceps, with or without the deflector tube, is mandatory (Fig. 4). If the deflector tube is not used, then the surgeon must ensure that appropriate protection against deep penetration of the flexible forceps is provided.

At the end of the procedure, the instruments are removed and the skin wound closed. A sterile dressing is applied, and the patient is monitored in the recovery room and returned to his or her room. Patients are allowed to ambulate as is comfortable, and they are discharged when they feel they are able to perform independently.

RESULTS

A total of 100 patients with 102 intervertebral discs were treated with percutaneous

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TABLE 1. Results of Percutaneous Lumbar Discectomy

<i>Surgical Level</i>	<i>Surgical Results</i>		<i>Available for Follow-up</i>	<i>Unavailable for Follow-up</i>	<i>Total</i>
	<i>Successes</i>	<i>Failures</i>			
L3-L4	9 (90%)	1 (10%)	10	2	12
L4-L5	69 (90%)	8 (10%)	77	5	82
L5-S1	3 (50%)	3 (50%)	6	—	6
Total	81 (87%)	12 (13%)	93	7	100

lumbar discectomy (Table 1). Ninety-three patients were available for follow-up examinations; three patients had died but had been followed for longer than 15 months postoperatively; and four patients could not be located for this review but had been followed for more than one year postoperatively. Fifty-nine of those patients available for follow-up examination had been followed for more than two years postoperatively, with a maximum follow-up period of six years. Of the 93 patients available for follow-up examination, 81 patients (87%), with 83 herniated nucleus pulposi, were judged to be successes, as they were pain-free and had returned to gainful employment and their preinjury activity levels. These patients stated that the procedure was successful in relieving their presenting symptoms. Twelve patients (13%) were failures and required repeat surgical procedures at the level of the presenting pathologic condition.

The three patients who died during the follow-up period had been followed for a minimum of 15 months postoperatively and were judged to have had an excellent result from the procedure based on clinical examination and the patients' activity levels. Causes of death were unrelated to the percutaneous lumbar discectomy and are reviewed below.

All patients met the inclusion criteria and had roentgenographic examinations of the lumbar spine. Ninety-two patients had myelograms, and all had positive myelographic findings consistent with their clinical examinations. The eight patients who did not have myelograms had correlative electromyogra-

phy studies as well as a correlative CT scan or MRI study. No instrument failure or breakage was experienced.

At the L3-L4 intervertebral disc level, 12 patients had percutaneous lumbar discectomy (see Table 1). Nine of these patients had successful results, while one patient had an unsuccessful surgical result, and two patients could not be located. The average follow-up period for this surgical level was 42 months, and all nine patients with successful results were followed for more than two years postoperatively. Two patients could not be located for this review but had been followed for more than one year postoperatively and had had an excellent result at the time of the last follow-up contact. Of the patients at this surgical level, two patients had simultaneous procedures at two levels and are included in the successful group. One patient had percutaneous lumbar discectomy at L2-L3 and at L3-L4 and has been followed for 17 months, and another patient had percutaneous lumbar discectomy at L3-L4 and at L4-L5 and has been followed for 39 months.

Eighty-two patients had percutaneous lumbar discectomy at the L4-L5 level, not including the patient mentioned above with a two-level procedure (see Table 1). A total of 77 of these patients were available for follow-up examination. Sixty-nine patients had successful results, three patients died during the follow-up period due to unrelated causes, two patients could not be located, and eight patients were surgical failures. The average follow-up period for the L4-L5 surgical level was 33 months, and 47 of the 69 successful

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results were followed for more than two years postoperatively. Of the three patients who died but had had successful results, one had been followed for more than two years, and two had been followed for more than 15 months. Two patients could not be located for this review but had been followed for more than one year postoperatively and had successful results at last follow-up examination.

At the L5-S1 intervertebral disc level, six patients had percutaneous lumbar discectomy (see Table 1). Three of these patients had successful results, while three patients had failed surgical results. The average follow-up period for this surgical level was 22 months, and one patient who had successful results was followed for more than four years postoperatively.

The average age of all of the patients was 46 years (standard deviation ± 14 years). The average age of the patients having an L3-L4 procedure was 52 years, and there were six men and six women. At L4-L5, the average age was 45 years, and there were 44 women and 38 men. The average age of the six patients (five men and one woman) who had procedures at the L5-S1 level was 38 years. No statistical differences in the sex or age of the patients could be found when examining either surgical level or outcome category.

Postoperative pain relief was experienced immediately by 71% of the patients, in one day by 75%, in two days by 79%, in three days by 81%, and in seven days by 87%. Eleven patients with successful results experienced pain relief after a prolonged postoperative period. Seven (58%) of the patients having failed results did not experience pain relief, but five patients (42%) with failed results experienced pain relief prior to discharge from the hospital. Seventy-four percent of the patients with successful results experienced pain relief prior to discharge from the hospital.

The average interval of conservative therapy prior to surgical intervention was 803 days, with 40 patients having received less than six months of conservative therapy. The

average pathology specimen weighed 1.9 g, and the average postsurgical hospitalization time was two days. No statistical significance could be established among outcome category and surgical level, occupation, duration of conservative therapy, original inciting cause of symptoms, or any other parameter.

Examination of the patient follow-up questionnaires found that of the nine patients with successful results at the L3-L4 level, four believed that they were cured of their presenting symptomatology (including both two-level patients), while five patients believed they were helped but not cured. One patient in the latter group had been reinjured, and two patients in the cured group had been reinjured. The time of postoperative pain relief was immediate for two patients in the cured category and four patients in the helped category. All of these patients have returned to their preoperative employment, seven within three months of surgery. The one failed patient did not have postoperative pain relief but has returned to his original preoperative employment.

At the L4-L5 surgical level, 43 patients stated that they have been cured, whereas 26 patients were helped but not cured. Thirty-four patients (80%) in the cured group and 14 patients (54%) in the helped group had immediate pain relief postoperatively. In the cured group, 33 patients returned to their original employment, three were employed in different jobs, including more strenuous positions, and seven patients were not working, including four patients who used the opportunity of surgery to retire. Of the helped but not cured patients, 18 have returned to their original employment, five have different jobs, and three are not working, including one patient who retired. In both groups (69 patients), 41 (69%) returned to work within one month, and 51 patients (74%) returned to work within three months postoperatively.

The three patients (all L4-L5 discs) who died during the follow-up period had stated during routine follow-up examinations that their pain relief was immediate, but their comments are not included because no sur-

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vey was completed. Two patients experienced fatal myocardial infarctions and one patient died of unknown causes. Of the eight failed patients at this level, six have returned to their previous employment following their subsequent surgery, while one is in a methadone maintenance program and one is receiving psychiatric treatment. Included in the failed category is one patient who was pain-free for greater than one year postoperatively but then reexperienced her original symptoms and subsequently was treated with lumbar laminectomy after the appropriate studies.

Of the L5-S1 surgical-level patients with a successful result, all had immediate pain relief and returned to their preoperative employment within three months. One failed patient had immediate pain relief but was subsequently reinjured, was treated with lumbar laminectomy, and is employed at his preoperative job. Two failed patients did not experience pain relief postoperatively, and only one has returned to his original job.

Postoperative CT scans were obtained in 22 patients. Sixteen scans were negative for the presence of a herniated nucleus pulposus at the surgical level and showed definitive changes of such from the preoperative study. The postoperative interval ranged from two to 21 months and included four patients who were, at the time, still complaining to some degree of their preoperative symptoms. Five scans, obtained from one to seven months postoperatively, were judged by the radiologist and surgeons to be unchanged from the preoperative study. Three of the five patients were in their first postoperative month, and all three patients were experiencing pain. Only one patient in this group was a surgical failure; the other patients eventually became asymptomatic. The surgical failure had a sequestered disc demonstrated at laminectomy.

One patient, who complained of pain at two months postoperatively, had a CT scan demonstrating a decrease in the size of the herniation at the surgical level. This patient complained of pain and became asymptomatic

over the ensuing month. Four patients had CT scans with herniated discs at levels other than the original surgical level; these herniations did not appear on their preoperative studies. Two of the four patients had been reinjured. All of the patients had symptoms that correlated with the roentgenographic findings of a herniation at a different level. One of these patients was reinjured and had a postoperative discogram at another institution that was negative for herniation at the level above the surgical level. All of these patients responded to conservative therapy.

The complications experienced with percutaneous lumbar discectomy have been reported previously¹¹ and were resolved during the immediate postoperative period. No other postoperative complications have been experienced. All of the patients in the present series received preoperative antibiotics, and there were no cases of postoperative infection.

Analysis of the failed surgical cases demonstrated that three patients were operated on by different physicians within the first postoperative month. One of these patients requested, and received, repeat laminectomies from two different physicians and still complains of the same symptoms.

One patient was reinjured after doing well initially. Repeat CT scan demonstrated lateral bony stenosis, confirmed by laminectomy at five months postoperatively. A second patient had degenerative spondylolisthesis, which subsequently required decompression at two months postoperatively. This patient had had a previous lumbar fusion for progressive spondylolisthesis at a lower level. A third patient was treated with lumbar decompression for lateral recess stenosis and sequestration at six months after percutaneous discectomy. No sequestration was evident on the preoperative studies. Another patient, although not having a laminectomy or repeat procedure is, as of this writing, enrolled in a drug-abuse and methadone maintenance program, although he did not disclose that fact to the treating physicians and is classified as a surgical failure.

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Five patients, pain-free during the initial postoperative period, were treated by laminectomy for symptoms identical to their presenting symptoms. Two of these patients were discovered to have sequestered disc herniations that were not apparent on the preoperative studies. One patient was operated on at six weeks postoperatively and the other at six months. Another two patients who were treated by later laminectomy had classic herniations at six weeks and nine months, respectively, after percutaneous discectomy. One patient became symptomatic at three years after percutaneous discectomy and was treated with decompression for newly diagnosed lateral recess stenosis that was not apparent on the original preoperative studies.

Workers' compensation was claimed by 13 of the patients with successful results and by three with failed results. The 13 workers' compensation patients with successful results took an average of 262 days to return to work with five patients returning to the same job, five to a different job, and three not returning to work. Of the three failed cases, two returned to the same job, while one did not return to work. The 72 patients with successful results who were not workers' compensation claimants returned to work after an average of 98 days, with 61 returning to the same job, three to different jobs, and eight not returning to work. Of the eight failed non-workers' compensation patients, seven returned to the same job, and one was a student.

Sixteen patients, 15 of whom had successful surgical results, were involved in litigation as a result of motor-vehicle accidents. Seventy patients with successful results and 11 patients with failed results were not involved in litigation. No statistical differences were found between return-to-work status and interval and surgical level, litigation, or workers' compensation claims.

DISCUSSION

Percutaneous lumbar discectomy is a valuable technique in the armamentarium used in the treatment of the herniated disc. In the

series presented here, 93% of patients were available for follow-up study, and of those, 81 patients (87%) represented successful results and 12 patients (13%) were surgical failures. Of the total patient population, 3% had died during the follow-up period and 4% could not be located. In these latter two groups, all patients were followed for a minimum of one year and had excellent results at the time of last follow-up contact but are not included in the surgical results. No differences were seen after two years of follow-up examination, and these results are identical to those reported previously.¹¹

These results compare favorably with those reported by Hijikata,⁶ Friedman,⁴ Hausmann and Forst,⁵ Onik *et al.*,¹⁷ Schreiber and Suezawa,¹⁸ Suezawa and Jacob,²¹ Monteiro,¹⁶ and Shepperd.¹⁹ The advantages of percutaneous lumbar discectomy are the high probability of success, the ease of performance, and the low risk.

In the present series, all patients met strict inclusion and exclusion criteria. Each patient had unremitting, persistent radiculopathy at L3-L4, L4-L5, or L5-S1; failure of appropriate conservative therapy; neurological impairment; correlative electromyography in the absence of correlative neurological deficits; positive tension signs; and correlative imaging studies.

At the L3-L4 surgical level, 83% of the patients were available for follow-up study, and of those, 90% were found to have had successful results, including two patients who had two-level simultaneous discectomies. Ninety-four percent of the patients with an L4-L5 discectomy were available for follow-up examination, and of those, 90% had had successful surgical results. Both the L3-L4 and the L4-L5 levels can be sufficiently decompressed to afford the patient a successful result from the percutaneous lumbar discectomy. At the L5-S1 level, all patients were available for follow-up study, but only 50% of them had had a successful surgical result. With proper positioning of the patient and the use of the newer flexible forceps, the L5-S1 disc space has become accessible to the

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percutaneous approach. However, greater care has to be exercised to avoid neural injury. The number of surgical cases at the L5-S1 intervertebral disc level is too small to make a conclusive recommendation; however, the initial results are encouraging.

Of the patients available for follow-up study, immediate pain relief was experienced by 61 patients, including four who were surgical failures. Fifty-one patients felt cured after the procedure, while 33 patients were helped but not cured. Although most of the patients with successful results had immediate pain relief, there were some patients who felt cured at the time of follow-up examination but whose pain took longer than one week to resolve. In patients with low-back pain, a continuum of symptoms and their relief were observed.

Sixty-three patients with successful results returned to their preoperative occupations, while eight patients returned to different occupations, including some that were more strenuous than the preoperative occupation, and ten patients did not return to work. Of the 71 patients who returned to work, a total of 61 (86%) did so within three months, with 39 (55%) returning to work within one month. The presence of litigation did not alter these results and did not increase the return-to-work interval postoperatively. Those patients with workers' compensation claims, however, did take a significantly longer time to return to work, perhaps reflecting the hidden rewards in the system for those patients with work-related injuries. In highly selected litigation and workers' compensation patients, the procedure might be performed successfully with the understanding that a longer recuperative period will be observed.

A few of the present patients had previous back injuries or surgical procedures at levels other than the index level prior to the percutaneous lumbar discectomy. The presence of either condition did not influence the surgical outcome. Patients with cauda equina syndrome, sequestered disc herniation, pedicle-induced nerve-root kinking, bony lateral recess stenosis, spinal stenosis, developmental

anomalies or tumors, and those patients with reherniation following laminectomy or chemonucleolysis are not candidates for this procedure because of the potential for anatomic distortion. In addition, patients with spondylolisthesis should be excluded.

The most common causes of failure were bony lateral recess stenosis and sequestered disc herniation that were not apparent on the initial preoperative studies. Studies have demonstrated that irregular myelographic defects and those at a distance from the disc space could indicate disc sequestration.³ None of the present patients, even in retrospect, had such defects. The present failures included patients who had been reinjured and then had had surgery at the index level. These cases were included in the failure category, since the relationship between inadequate discectomy and susceptibility to reinjury has not been established. In addition, patients with psychosocial disorders are not candidates for the procedure, as evidenced by two of the patients reported as failures.

The complications experienced with percutaneous lumbar discectomy have been previously reported by the present authors¹¹ as well as by Schreiber and Suezawa¹⁸ and Blankstein *et al.*¹ The latter two groups of authors have each reported on cases of disc-space infection and vertebral osteomyelitis postoperatively. In both of these reported studies the patients did not receive prophylactic antibiotics. All of the patients in the series reported here received preoperative prophylactic antibiotics, and there were no cases of postoperative infection or discitis. The present authors have previously reported two cases of psoas hematoma that responded to conservative therapy. If periannular bleeding is encountered, a single-tube hemovac is left in the wound for 24 hours and then withdrawn. No other postoperative complications have been experienced since this earlier report. No postoperative neurological or vascular complications have been encountered.

Postoperative CT scans were obtained in 22 patients. Sixteen scans indicated that there was no herniation at the surgical level.

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Adequate fenestration of the annulus is essential. In a recent study by the present authors,⁹ intradiscal pressure measurements were made prior to and immediately following the annular fenestration. The observed rapid decrease of intradiscal pressure following dorsolateral fenestration of the annulus suggests that pressure reduction plays an important role in the reduction of sciatic pain following percutaneous discectomy. Hijikata⁶ has shown that a 4- to 5-mm fenestration of the annulus may remain patent for up to nine months following percutaneous discectomy.

Percutaneous lumbar discectomy through the posterolateral approach is effective, safe, and cost efficient, with decreased hospitalization and postoperative recovery time. To be considered a candidate for percutaneous lumbar discectomy, all patients must (1) have unremitting, persistent radiculopathy; (2) have failed appropriate conservative therapy; (3) demonstrate neurological impairment or have correlative electromyography in the absence of correlative neurological deficits; (4) demonstrate positive tension signs; and (5) have correlative imaging studies. The exclusion criteria are rigorous and must be considered prior to performing the procedure. Meticulous patient selection, familiarity with the operative technique, anatomical structures of the lumbar spine, and proper use of the instruments are paramount in achieving a successful outcome in percutaneous lumbar discectomy. A sterile surgical environment, correct positioning of the needle at the onset of the surgery, and adequate annular fenestration also ensure a successful result and minimize the incidence of unsatisfactory results and potential complications. Long-term follow-up study of the present patient population will continue to provide data for more objective evaluation of the percutaneous approach.

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Posterolateral Percutaneous Suction-Excision of Herniated Lumbar Intervertebral Discs

Report of Interim Results

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Posterolateral Percutaneous Suction-Excision of Herniated Lumbar Intervertebral Discs

Report of Interim Results

PARVIZ KAMBIN, M.D.* AND STEVEN SAMPSON, M.D.**

Fifty consecutive patients with intractable sciatic pain, positive root tension signs, correlative myelography, and neurological impairment were treated by percutaneous lateral discectomy (PLD). Under local anesthesia and C-arm fluoroscopy control, an 18-gauge needle, introduced into the intervertebral disc dorsolaterally, entered the skin at approximately 9 cm from the midline. A Kirschner wire replaced the stylet of the needle, and the needle was withdrawn. The introduction of a specially designed cannulated trocar over the K-wire facilitated precisional insertion of the instruments. This step was followed by the introduction of a sheath with an internal diameter of 4.9 mm over the trocar. The sheath was held against the annulus fibrosis, and the cannulated trocar was removed. The annulus was windowed and the herniated disc material evacuated by instruments and suction. Evaluations were made with Macnab's criteria. Excellent and good results were obtained in 88% of patients. The mean length of hospital stay after operation was 2.3 days. The operative time, blood loss, and morbidity were minimal, and no serious complications were en-

countered. In carefully selected patients, PLD appears to be safe, effective, and cost-efficient.

The clinical syndrome of ruptured lumbar disc and its surgical "decompression" through a posterior approach was first reported by Mixter and Barr⁸ in 1934. In their series of 19 patients, 11 had herniation in the lumbar area. Since that time, lumbar disc herniation and its management has remained a profound medical and socioeconomic problem.

The percutaneous posterior lateral approach to the vertebral bodies for biopsy purposes was first described in 1948 by Valls *et al.*⁹ and in 1956 by Craig.² In 1975, Hijikata⁴ reported follow-up results on 14 of 30 patients who were treated by percutaneous nucleus extraction. A 2.6 mm-external-diameter cannula was used and an average amount of 1.3 gm of nucleus removed. Sixty-four percent of the patients in this study were classified as having an excellent result. Blum *et al.*¹ have reported their limited experience with percutaneous nucleotomy through a posterior lateral approach using a technique devised and previously reported by Hijikata. In May of 1983, Hoppenfield⁵ presented percutaneous removal of herniated

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TABLE 1. Findings Predicting Disc
Herniation Prior to Operation

+Myelogram	50
+Tension sign	50
+CAT scan	42
Neurodeficits (one or two neurological deficits) were present in 19 patients.	
Extensor weakness	19
Reflex abnormality	8
Sensory deficit	10
Atrophy	4
Positive EMG findings	40

lumbar disc through the tube technique introduced posterolaterally.

Friedman³ recently reported percutaneous discectomy on nine patients with herniated lumbar discs, using Jacobson's technique. A speculum, through a one-inch incision over the iliac crest, and a 40-French chest tube were introduced. The annulus was incised and disc material removed. In this operation, the instruments are introduced laterally, and the author recommends a specific screening process prior to surgery for identification of aberrant retroperitoneal structures that may lie in the surgical path. Gastrografin (E. R. Squibb and Sons, Inc., Princeton, New Jersey) and transaxial scanning were used.

The senior author's experience with percutaneous lateral discectomy began in 1973, when he combined laminectomy with dorso-lateral evacuation of nucleus with the use of Craig instruments.⁶ This paper describes the detailed surgical technique of percutaneous posterior lateral discectomy and evaluates the 50 consecutive patients treated by this method.

MATERIALS AND METHODS

Fifty consecutive patients (mean age, 49 years) were treated by percutaneous lateral discectomy.

TABLE 2. Outcome Assessment*

Excellent	30	88%
Good	14	
Fair	3	12%
Poor	3	

* Macnab's Standard Criteria on Return to a More Normal Functional Level (modified).

All patients failed a conservative trial of bed rest, anti-inflammatory drugs, physical therapy, and exercise. All patients presented signs and symptoms of unremitting radiculopathy at the L3-L4 and L4-L5 levels. These patients demonstrated objective evidence of paravertebral muscle spasms, limitation of lumbar mobility, and positive tension signs (straight-leg-raising test, Lasègue, and sitting root pain). Nineteen patients in this group exhibited one or two neurological deficits (Table 1). All 50 patients had positive correlative myelography. Forty-two patients were exposed to CAT scan studies, which showed added soft-tissue density at the site of disc protrusion. Electromyogram study was performed in 40 patients, revealing abnormal findings consistent with nerve root compression.

The follow-up period of the 50 patients varied from 12 to 41 months (mean, 27 months). The follow-up examination consisted of chart review, interview, and physical examination. These patients were evaluated according to modified Macnab's standard criteria⁷ (Table 2) in regard to a return to a normal functional level as follows: excellent—indicates that the patient was free of pain, had no restriction of mobility, and was able to return to normal work and activities; good—indicates occasional pain and ability to return to modified work; fair—indicates some improvement; however, the patient is still handicapped and unemployed; poor—indicates continued objective symptoms of root involvement, and further surgical intervention was required.

Excellent and good results were considered successes, while fair and poor results were considered failures. CAT scans were obtained after the operation to document the results of decompression following the percutaneous lateral discectomy.

TECHNIQUE OF PERCUTANEOUS LATERAL DISCECTOMY

At the time of surgery, the patient is placed in the prone position and readied for C-arm display. The level of the disc space is marked 9–10 cm from the midline on the patient's symptomatic side; however, a distance of 8–9 cm may be adequate for slim patients. Following infiltration of a local anesthetic, an 18-gauge needle is inserted at an angle of 35°–45°. The needle is advanced to the annulus fibrosis at the two or ten o'clock position with reference to the spinous process at that level. This positioning tends to facilitate the evacuation and decompression of the herniated nuclear material. The correct positioning of the needle is an important initial step. An attempt should be made to introduce the needle parallel to the vertebral plates and to the center of the disc, as is visualized in the anteropos-

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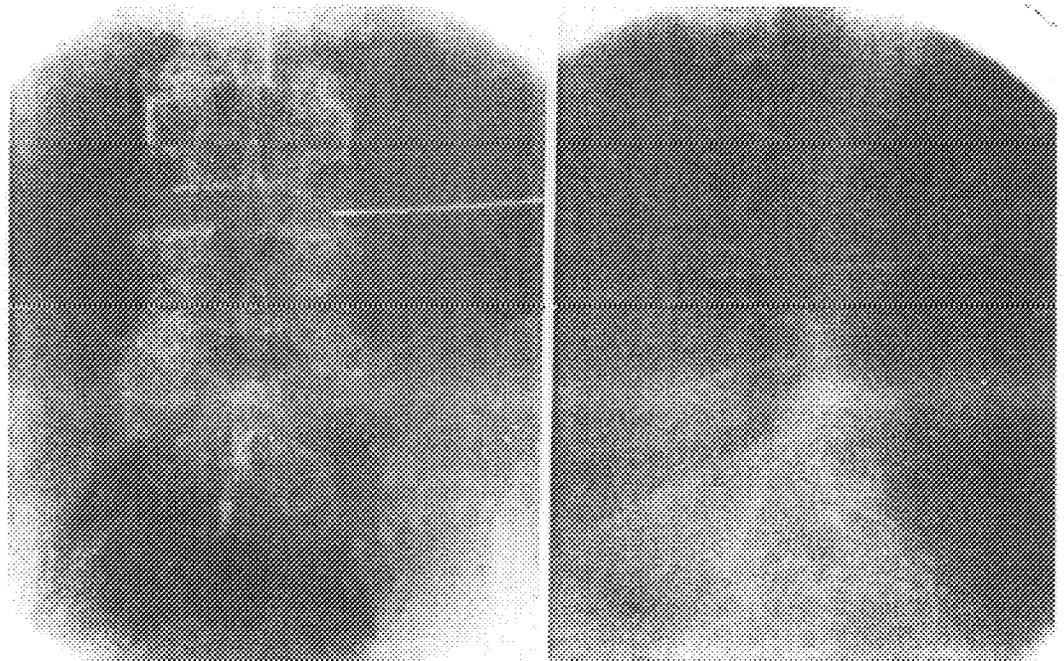


FIG. 1. Anteroposterior and lateral roentgenograms showing correct position of needle at L4-L5.

terior and lateral X-ray projection (Fig. 1). When the needle is correctly positioned, a .028-inch-diameter Kirschner wire is introduced through the 18-gauge needle, and the needle is then withdrawn.

A specially designed cannulated blunt trocar (external diameter, 4.0 mm; length, 19.0 cm) is passed over the K-wire and is directed toward the annulus (Fig. 2). The cannulated trocar permits precision insertion of the instruments, avoiding undue injury to the soft-tissue structures. As soon as the position of the trocar is firm and its direction is established, the guide wire is removed, thus avoiding possible migration of the guide pin.

Because the operation is performed under local anesthesia, the possibility of penetration of the spinal nerve by the inserted needle is remote. However, in this case, the withdrawal of the guide pin prior to full insertion of the trocar permits freedom and mobility of the nerve root and allows the blunt end of the 4 mm trocar to bypass it. Radiographic documentation of the position of the trocar in the anteroposterior and lateral planes is then obtained (Fig. 3). A sheath or cannula (internal diameter, 4.9 mm; external diameter, 6 mm; length, 16.0 cm) is then passed over the blunt trocar and is held firmly against the annulus while the blunt trocar is removed.

The entrapment of the nerve root under the edge of the sheath is extremely painful and is unlikely

to occur. At this time, a sharp needle is introduced to the sheath, perforating the annulus and walking around its internal perimeter. The puncture of the annulus with a sharp instrument should not produce radicular pain (anterior thigh in L-4, buttock, and lateral leg, when L-5 root is involved).

A small cutting instrument (external diameter, 2.5 mm) centered on a hollow tube and fitting snugly inside the sheath is used to permit the rapid decompression of the intervertebral disc with less pain and discomfort. A larger cutter (external diameter, 4.0 mm) is then used to enlarge the annular fenestration. Under radiographic control, the annulus is windowed with firm rotatory movement with the cutting instruments. When the cutter is fully inserted, it extends 2 cm behind the tip of the inserted sheath. This step of the procedure is usually painful, and the patient may complain of referral pain to the lower extremity. Additional analgesics should be administered by the anesthesiologist at this time.

The straight and curved forceps are then introduced through the sheath into the disc space (Figs. 4 and 5). The length of the forceps only permits a 2 cm penetration behind the tip of the sheath.

Evacuation of additional disc material is aided by simple aspiration with a 50 cm³ Luer-Lok syringe fitted to the cutting instrument or the forceps deflector. The procedure is repeated until no further

(20)

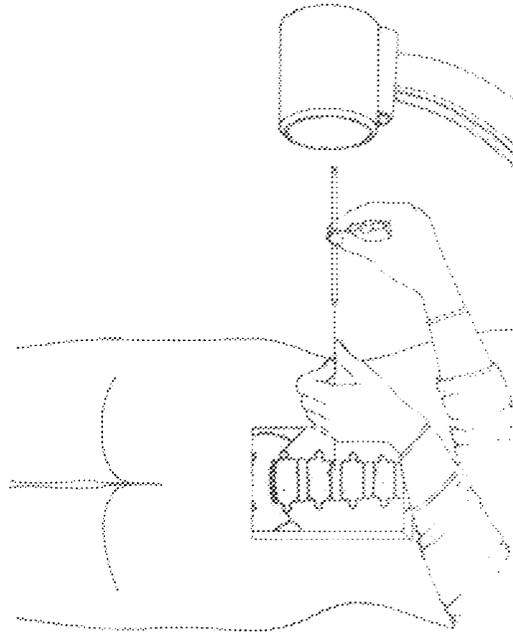


FIG. 2. Blunt cannulated trocar directed toward annulus over K-wire.

disc material can be obtained. The addition of forceps deflector and flexible forceps to the basic instruments facilitates further disc extraction.

RESULTS

Forty-two patients had disc herniation at the L4-L5 level, and eight patients at L3-L4. The mean duration of surgical time, including time for anesthesia induction, was one hour, and the mean estimated blood loss was 10 cm³. The mean amount of disc material removed at surgery was 2.3 gm.

Within the first 24 hours following the operation, 84.2% of patients had significant relief of sciatica. The mean hospitalization period after surgery was 2.3 days. Eighty percent of these patients were rated as good or excellent at the end of the follow-up period.

Forty-two patients had positive CAT scan evaluations prior to surgery, and 18 of these patients were exposed to a repeat CAT scan study following surgery. Fourteen patients showed no evidence of disc herniation after

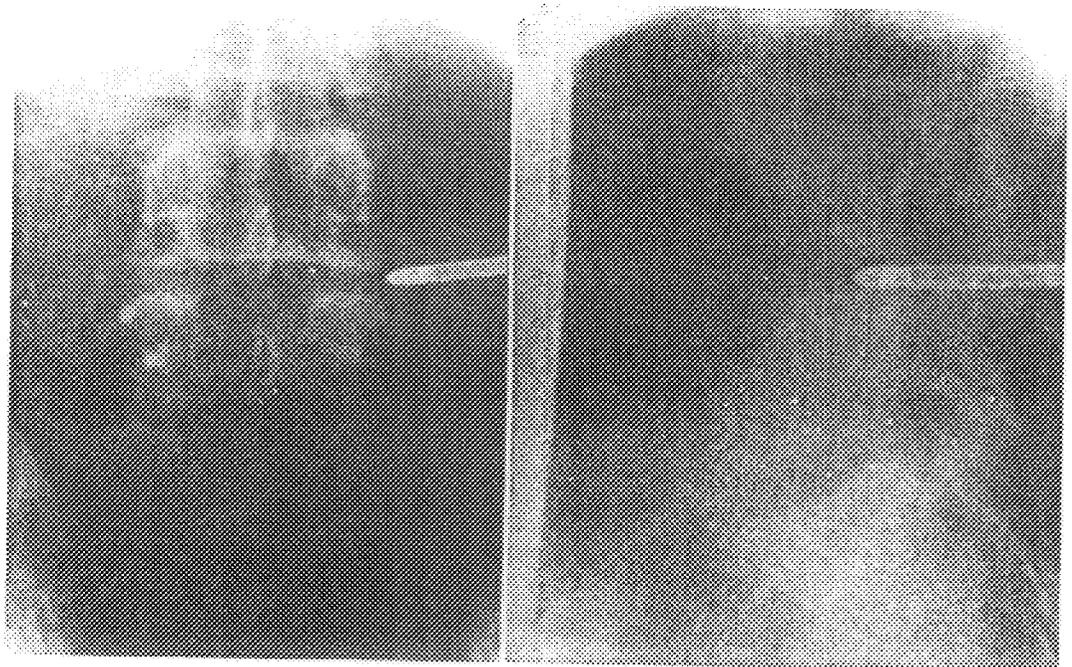


FIG. 3. Roentgenographic documentation of position of trocar.

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the operation (Figs. 6 and 7). In four patients, the interpretation was not definitive.

Eighty-eight percent of the patients were rated as good or excellent and were thus considered successes. Twelve percent were rated fair and were considered failures, with four patients subsequently requiring laminectomy. A sequestered disc was found in two patients and was excised. The remaining two patients had degenerative spondylolisthesis, bulging annulus, and lateral stenosis, which required surgical decompression. The diagnosis of sequestration had not been made prior to the operation either by myelography or in the CAT scan evaluation. In retrospect, the remaining two patients were poor candidates for percutaneous posterior lateral discectomy.

Morbidity was extremely low. None of the patients experienced neurologic deficit, wound infection, or disc space infection following the operation. One patient showed transient evidence of weakness and sensory deficit after the operation that was due to the use of a local anesthetic. This disappeared within a few

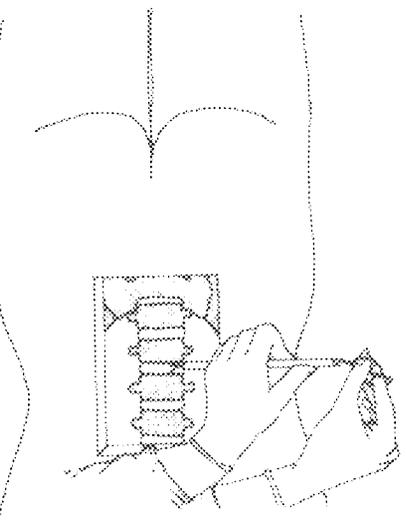
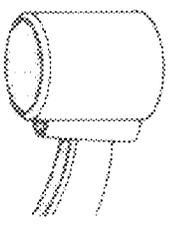


FIG. 4. The straight and curved forceps are used for the evaluation of the nucleus

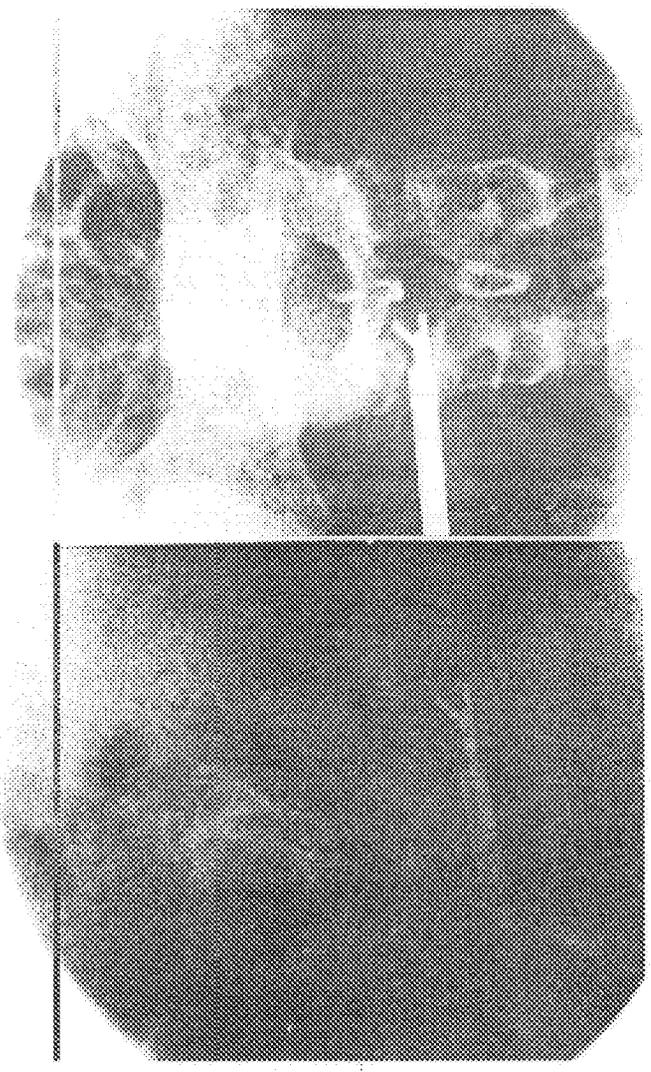


FIG. 5. Roentgenographic documentation of position of the forceps.

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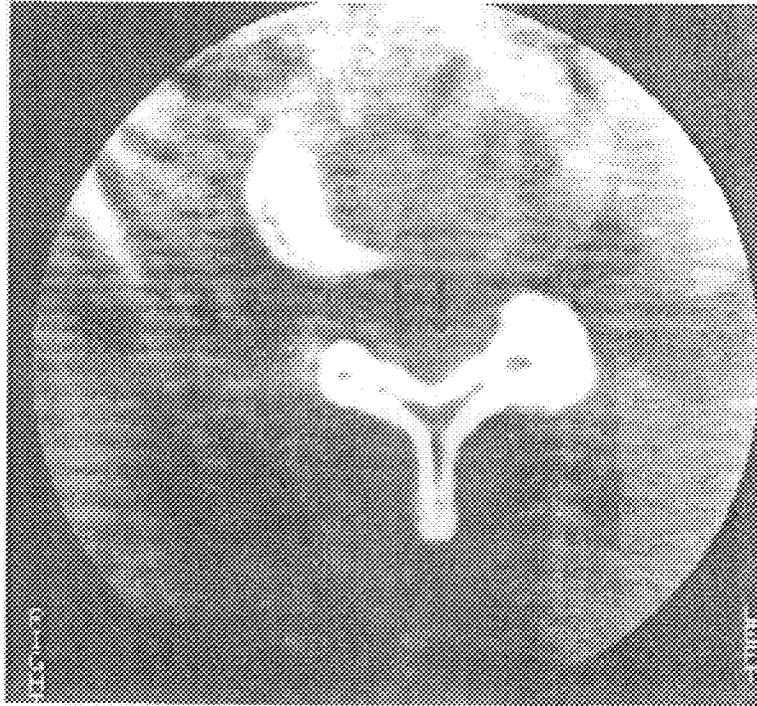


FIG. 6. CAT scan study prior to operation demonstrating a large disc protrusion at L4-L5.

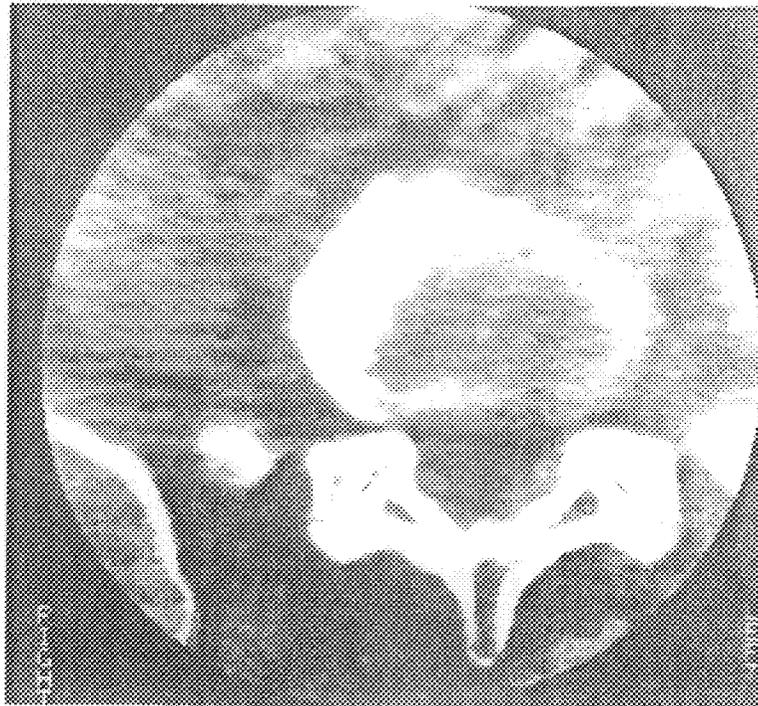


FIG. 7. CAT scan study after operation showing the reduction in the size of the added soft-tissue density following the surgery.

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hours. Two days after discharge (four days after operation), two patients complained of severe pain on the anterior thigh and anteromedial aspect of the leg on the side where the surgical procedure was performed. On physical examination, both patients exhibited tenderness below the inguinal ligament, and the femoral pulses were intact. Manual compression of the femoral triangle reproduced and intensified their pain, while flexion of the hip joint provided relief. One patient showed diminished patella reflex. No sensory deficit was found, and the radicular pain, which was present prior to the operation, had subsided. Their tension signs were negative. The signs and symptoms subsided with bed rest, analgesics, and elevation of the painful extremity.

DISCUSSION

This paper represents the first prospective study of 50 consecutive patients who were treated by percutaneous lateral discectomy. The results show that this operation is safe, effective, and relatively cost-efficient.

The pain following the operation in the anterior thigh and leg, which occurred in two patients, did not represent a serious complication and was attributed to bleeding from the site of the surgery, psoas hematoma, and perhaps the extraperitoneal descent of the blood in the course of iliopsoas muscle and its accumulation in the femoral triangle.

Advantages of percutaneous lateral discectomy include the avoidance of epidural bleeding and perineural fibrosis, elimination of reherniation through the intraoperatively induced annular fenestration, preservation of spinal stability, and establishment of a portal for future herniation away from the neural elements. Future surgical procedures are not compromised, and percutaneous lateral discectomy is a more cost-effective procedure with decreased operative time and hospitalization period accompanied by an earlier return to work.

The disadvantages of percutaneous lateral discectomy include the limitation of accom-

plishing nerve root decompression at L5-S1 and the inability to eliminate root compression produced by causes other than disc herniation. Percutaneous discectomy is contraindicated in cauda equina syndrome, and the sequestered disc cannot be removed by this method.

Careful screening prior to the operation and patient selectability remain instrumental in achieving a successful outcome following this procedure.

Four prerequisites must be met: (1) persistent sciatic pain and failure of response to conservative therapy; (2) neurological impairment as reflected by sensory deficit, reflex abnormality, motor weakness, or electromyographic evaluation; (3) presence of positive tension signs; and (4) clear positive correlative myelography.

The follow-up period following the operation in this study is relatively short. However, in light of the simplicity of the procedure, its relative safety, the minimal associated morbidity, and the relief of pain, even for a period of more than two years (mean follow-up period), the follow-up reports are encouraging and worth consideration.

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PERCUTANEOUS LUMBAR DISCECTOMY: THE GRADUATE HOSPITAL EXPERIENCE

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INTRODUCTION

Lumbar disc herniation remains a major national health problem. The majority of patients with radicular pain secondary to disc protrusion do respond to conservative management. When surgical intervention becomes necessary, the patient and surgeon have three alternatives to choose from: laminectomy and discectomy, chemonucleolysis, and percutaneous posterolateral discectomy.

The concept of decompression of the nucleus, rather than direct visualization and excision of the protruded part of the disc, is not new. In 1951, Hult reported the relief of both low back and sciatic pain in thirty patients following fenestration of the annulus through an open retroperitoneal approach. The percutaneous posterolateral approach for vertebral body biopsy was first described by Craig. Since Mixter and Barr's classic description of the association of a herniated nucleus pulposus with sciatica and treatment of this condition by laminectomy, surgeons have desired a more precise and less destructive surgical approach.

Percutaneous discectomy is less destructive than laminectomy in the surgical management of dorsolateral nuclear protrusion and the percutaneous approach permits the decompression and evacuation of the bulge of the herniation without

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entrance into the spinal canal and without destruction of the facets and the articular processes. The advantages of percutaneous discectomy include avoidance of epidural bleeding and perineural fibrosis, elimination of reherniation in the spinal canal through the surgically induced annular fenestration, preservation of spinal stability, and establishment of a portal away from the neural elements for future herniation. In addition, future surgical procedures are not compromised and the hospitalization is more cost effective than traditional approaches as the operating room and hospitalization times are decreased.

MATERIAL AND METHODS

All patients were eligible for the procedure if they met the following criteria:

- Unremitting, persistent radiculopathy at L3-L4, L4-L5, or L5-S1
- Failure of appropriate conservative therapy
- Neurological impairment as reflected by sensory deficits, reflex abnormalities, and motor weakness
- Correlative electromyography in the absence of correlative neurological deficits
- Positive tension signs
- Correlative imaging studies

The inciting episode, work history, general medical health, psychosocial environment, and description of the patient's symptoms were recorded on a standardized report form. The physical examination findings, and any changes noted at each visit, and the results of the diagnostic studies were duly recorded. Patients with a sequestered disc herniation, bony lateral recess stenosis, spinal stenosis, and pedicle induced nerve root kinking were excluded. Patients with developmental anomalies or tumors and those patients

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with reherniation following laminectomy or chemonucleolysis were not candidates for this procedure because of the potential for anatomic distortion. All patients underwent plain roentgenographic examination of the lumbar spine. All patients underwent metrizamide lumbar myelography which was, when necessary, followed by computerized tomographic scans. Patients who were allergic to iodinated compounds did not undergo myelography, and in these patients correlative electromyography and CT scans were obtained. Informed consent was obtained from all patients. All of the patients in the study received prophylactic preoperative antibiotics.

Post operative examinations were made at one, two and four weeks, then at three, six and twelve months followed by annual examinations. The follow-up examination consisted of chart review, physical examination and patient interviews. A six part questionnaire was filled out by all patients contacted and included detailed questions about activity level, work history, back pain and pain relief postoperatively. The surgical results were analyzed using modified MacNab's criteria for function levels.

RESULTS

One hundred patients with one hundred and two intervertebral discs, underwent percutaneous lumbar discectomy. Ninety three patients were available for follow-up, three patients had died but had been followed for greater than fifteen months postoperatively, and four patients could not be located for this review but had been followed for greater than one year postoperatively. Fifty nine of those patients available for follow-up had been followed for greater than two years post operatively with maximum follow-up of six years. Of the ninety three patients available for follow-up a total of eighty one patients (87%) with eighty three herniated nucleus pulposes were judged to be successes as they were pain free and had returned to gainful employment and their

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preinjury activity levels. These patients stated that the procedure was successful in relieving their presenting symptoms. Twelve patients (13%) were failures as they underwent repeat surgical procedures at the level of presenting pathology regardless of the length of postoperative follow-up.

The three patients that had died during the follow-up period were followed for a minimum of fifteen months postoperatively and were judged to have an excellent result from the procedure based on the clinical examination and the patient's activity level. The causes of death were unrelated to the percutaneous lumbar discectomy and are reviewed below. All patients met the inclusion criteria and had roentgenographic examinations of the lumbar spine. Ninety two patients underwent myelography and all had positive myelographic findings consistent with their clinical examination. The eight patients without myelograms had correlative electromyography studies as well as a correlative CT scan or magnetic resonance imaging study. No case of instrument failure or breakage was experienced.

At the L3-L4 intervertebral disc level, twelve patients underwent percutaneous lumbar discectomy. Nine of these patients had successful results while one patient was a failed surgical result and two patients could not be located. Of the patients at this surgical level, two patients had two level simultaneous procedures and are included in the successful group. One patient underwent L2-L3 and L3-L4 percutaneous lumbar discectomy and has been followed for 17 months and another patient underwent L3-L4 and L4-L5 percutaneous lumbar discectomy and has been followed for 39 months.

Eighty two patients underwent percutaneous lumbar discectomy at the L4-L5 level, not including the patient mentioned above with a two level procedure. A total of seventy seven patients were available for follow-up. Sixty nine patients had successful results, three patients died during the follow up period

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due to unrelated causes, two patients could not be located and eight patients were surgical failures. Of the three patients who died but were successful results one was followed for greater than two years and two were followed for greater than fifteen months. Two patients could not be located for this review but had been followed for greater than one year postoperatively and were successful results at last follow-up.

At the L5-S1 intervertebral disc level, six patients underwent percutaneous lumbar discectomy. Three of these patients had successful results while three patients were failed surgical results.

Post operative pain relief was experienced immediately by 71% of the patients. Of note is that seven of the failed cases (58%) did not experience pain relief while five patients (42%) with a failed result experienced pain relief prior to discharge from the hospital. No statistical significance could be established between outcome category, surgical level, occupation, duration of conservative therapy, original inciting cause of the patients' symptoms or any other parameter.

Analysis of the failed surgical cases demonstrated that three patients were operated on by different physicians within the first postoperative month. One of these patients requested, and received, repeat laminectomies from two different physicians and still complains of the same symptoms. One patient was reinjured after doing well initially. Repeat CT scan demonstrated lateral bony stenosis, confirmed by laminectomy at five months postoperatively. One patient had degenerative spondylolisthesis which subsequently required decompression at two months postoperatively. This patient had a previous lumbar fusion for progressive spondylolisthesis at a lower level. Another patient underwent lumbar decompression for lateral recess stenosis and sequestration at six months post percutaneous discectomy. No sequestration was evident on the preoperative

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studies. One patient, although not having undergone laminectomy or repeat procedure, was, and is enrolled in a drug abuse and methadone program although he did not disclose that fact to the treating physicians, and as such is classified as a surgical failure.

Five patients, pain free during the initial post operative period, underwent laminectomy for symptoms identical to their presenting symptoms. Two of these patients were discovered to have sequestered disc herniations that were not apparent on the preoperative studies. One patient was operated on six weeks postoperatively and the other at six months. Two patients underwent laminectomy and had classic herniations at six weeks and nine months post percutaneous discectomy. One patient became symptomatic at three years post percutaneous discectomy and underwent decompression for newly diagnosed lateral recess stenosis that was not apparent on the original preoperative studies.

Workers' compensation was claimed by thirteen of the patients with successful results and by three with failed results. The thirteen workers' compensation patients with successful results took an average of 262 days to return to work with five returning to the same job, five to a different job and three not returning to work. Of the three failed cases two returned to the same job while one did not return to work. The seventy two successful result patients who were not workers' compensation claimants returned to work at an average of 98 days with 61 returning to the same job, three to different jobs and 8 not returning to work. Of the eight failed non worker's compensation patients seven returned to the same job and one was a student.

Litigation was a result of motor vehicle accidents and was involved in sixteen patients, fifteen of whom had successful results. Seventy patients with successful results and eleven patients with failed results were not involved in litigation. No statistical differences were found between surgical level,

litigation, workers' compensation and return to work status and interval.

DISCUSSION

Percutaneous lumbar discectomy is a valuable technique in the armamentarium used in the treatment of the herniated disc. Ninety three percent of the patients were available for follow-up, and of those, eighty one patients (87%) were judged to be successes as they were pain free and had returned to gainful employment and their preinjury activity levels. Twelve patients (13%) were failures as they underwent repeat surgical procedures at the level of presenting pathology, regardless of the length of postoperative follow-up. Each patient had unremitting, persistent radiculopathy at L3-L4, L4-L5, or L5-S1, failure of appropriate conservative therapy, neurological impairment, correlative electromyography in the absence of correlative neurological deficits, positive tension signs, and correlative imaging studies.

Both the L3-L4 and L4-L5 surgical levels can be sufficiently decompressed to afford the patient a successful result from the percutaneous lumbar discectomy. At the L5-S1 level follow-up was one hundred percent but only 50% of the patients had a successful surgical result. With proper positioning of the patient and the use of the newer flexible forceps, the L5-S1 disc space has become accessible to the percutaneous approach.

A few of our patients had previous back injuries or surgical procedures at levels other than the index level prior to the percutaneous lumbar discectomy. The presence of either condition did not influence the surgical outcome.

The most common causes of failure were bony lateral recess stenosis, sequestered herniation, that was not apparent on the initial preoperative studies, and improper sheath positioning leading to inadequate evacuation. Studies have demonstrated that irregular myelographic defects and those at a distance from the disk space could indicate disc sequestration. None of the

patients, even in retrospect, had such defects. Our failures included patients who had been reinjured and then had surgery at the index level. These cases are included in the failure category as the relationship between inadequate discectomy and susceptibility to reinjury has not been established. In addition, those patients with psychosocial disorders are not candidates for the procedure as evidenced in two of the patients reported as failures.

Schreiber and Suezawa and Blankstein et al have each reported on cases of disc space infection and vertebral osteomyelitis post operatively. In both reports the patients did not receive prophylactic antibiotics. All of the patients in our series received preoperative prophylactic antibiotics and there were no cases of postoperative infection or discitis. We have previously reported two cases of psoas hematoma which responded to conservative therapy. If periannular bleeding is encountered a single tube hemovac should be left in the wound for twenty four hours and then withdrawn. No other post operative complications have been experienced since our previous report. We have not encountered any post operative neurological or vascular complications.

Percutaneous lumbar discectomy is effective, safe, cost efficient and the risk of neurovascular injury is of minimal concern. Meticulous patient selection, familiarity with the operative technique and the anatomical structures of the lumbar spine and the proper use of the instruments are paramount in achieving a successful outcome in percutaneous lumbar discectomy. A sterile operating room environment, correct positioning of the needle at the onset of the surgery and adequate annular fenestration also ensures a successful result and minimizes the incidence of unsatisfactory results and potential complications.

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SELECTION OF THE SURGICAL PATIENT
FOR PERCUTANEOUS LATERAL DISCECTOMY

By: Mark B. Stern, M.D.

The most important factor in the success of percutaneous lateral discectomy, as it is in the success of any surgical procedure, is the selection of the "appropriate patient." The "appropriate patient" has uniformly been described in the literature as one in whom all conservative treatment has failed, whose symptoms are still present and disabling, and whose only apparent recourse is to surgical correction--in this case, lumbar laminectomy.

It is generally appreciated by most physicians that 60 to 80 percent of patients with low back pain and sciatica can be relieved by conservative measures, usually consisting of bed rest, heat or ice, analgesics, anti-inflammatories, exercises, bracing, and in some cases epidural steroids. A small percentage of patients with back pain and sciatica have extruded disc fragments, tumors, spinal instability, stenosis and cauda equina syndrome, and can only be helped by conventional surgical procedures. This leaves us with 15 to 35 percent of patients with low back pain and sciatica that might be helped by percutaneous lateral discectomy.

The criteria that must be met for consideration of a patient for percutaneous lateral discectomy are:

1. Severe unremitting low back pain and sciatica;
2. Positive neurological findings in the affected leg;

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3. Corroborative imaging studies (MRI, CT scan, myelogram) showing disc protrusion and neural impingement;
4. Failure of conservative treatment;
5. Positive tension signs in the affected leg.

Following a complete history, physical examination and x-rays of the lumbar spine, the symptomatic patient should be treated with all of the conservative modalities listed above in an attempt to relieve him. My own protocol is to insist on at least two weeks of bed rest, using the analgesics, anti-inflammatories, and ice or heat. If the patient is improving, then this form of treatment is continued until a plateau is reached or the patient is cured. Two weeks is an arbitrary figure with no investigational basis to validate it.

After two weeks of bed rest, most patients are feeling better and are gradually mobilized. If the symptoms begin to return, or if the patient is no better after two weeks of treatment, a MRI of the lumbar spine is ordered. I use the MRI in preference to myelogram or contrast enhanced CT because it is a non-invasive, non-radiation procedure with images and accuracy as good or better than the other two. I have not used discograms for these same reasons.

If the MRI shows a herniated disc with neural impingement and little other pathology, then the patient becomes a candidate for percutaneous lateral discectomy. If central spinal stenosis secondary to degenerative changes is also present, then the surgeon must evaluate the MRI and determine whether the patient will obtain significant relief from a percutaneous lateral discectomy. In most cases the patient will benefit more from a decompressive laminectomy.

In a small number of cases with mild focal bulges of the disc on MRI, epidural steroids are used. Although the recent orthopedic literature refutes their effectiveness, I have had a number of cases in which it has caused a remission of symptoms for an indefinite period of time.

As with the term conservative treatment, there is also a wide variation and lack of uniformity in the nomenclature used to describe the pathological process observed in the MRI. The terms mild, moderate and severe herniation, extruded fragment and sequestered fragment, are used with many different interpretations. In order to better define terms and give them a universal meaning, a disc protrusion on MRI of 1-2 millimeters is mild and might well be considered to be within normal limits unless it impinges on neural tissue. A protrusion of 2-4 millimeters is considered moderate and of more clinical significance. A protrusion of 5 millimeters or more is severe.

One must remember also that the MRI is done in a supine position, and as the patient sits or stands the disc protrusion may increase markedly. An extruded fragment is considered to be confined by the posterior longitudinal ligament, although it may have migrated proximal or distal to its disc space. A sequestered disc on the other hand is a fragment that is free in the epidural space. In my experience, the only disc protrusions that are amenable to percutaneous lateral discectomy are those that have not violated the confines of the annulus. Once a portion of the disc has extruded outside the annulus, even though it maintains its continuity with the parent disc, I think the chance of success with percutaneous lateral discectomy is small.

Another consideration in selecting the patient for percutaneous lateral discectomy is the patient who has recurrent severe low back pain without sciatica. At this time, this is a gray area in treatment. There are a number of reports of percutaneous lateral discectomy helping these patients if all conservative measures have failed, and a MRI shows a central disc herniation impinging significantly on the theca at the appropriate level. I have had one case in this category which was successfully treated by percutaneous lateral discectomy.

The factors that would exclude a patient from being considered for percutaneous lateral discectomy are:

1. Evidence of an extruded or sequestered disc fragment;
2. The possibility of cauda equina syndrome;
3. A very narrow and arthritic L5-S1 disc space. This disc space is difficult to enter with normal anatomy, and when narrowed and arthritic it is almost impossible to perform an adequate percutaneous lateral discectomy;
4. Severe degenerative central stenosis or lateral recess stenosis;
5. An unstable personality, an addict, malingerer, or patient with multiple back surgeries who has not improved.

Although percutaneous lateral discectomy in its infancy appears to be a very promising procedure in relieving back pain and sciatica, the most important factor in the success or failure of the procedure is the use of strict criteria for selecting the "appropriate patient."

Document Separator



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 22 1992

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Eric Bannon
Regulatory Affairs Manager
Dyonics, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K900070
Percutaneous Arthroscopic Micro
Discectomy System
Regulatory Class: II
Dated: December 28, 1989
Received: January 4, 1990

Dear Mr. Bannon:

The following supercedes our letter dated February 16, 1990.
We have amended the limitations on the intended uses.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device system is substantially equivalent to device systems marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitation: all labeling for this device system, including package label and labeling included within the package, must prominently state that the Video Discoscope Set of this system, placed under fluoroscopic support, is intended only for visualization of lumbar herniated discs.

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.

You may market your device system under the above limitations as a class II device. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device system 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 system as described. An FDA finding of substantial equivalence of your device system to a legally marketed predicate device results in a classification for your device system and permits your device system to proceed to the market, but it does not mean that FDA approves your device system. Therefore, you may not promote or in any way represent your device system or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device system please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. 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,



David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health



CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

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4

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 2 - Mr. Eric Bannon

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Sincerely yours,

David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
410	Myers	4/28/92	410	Smith	5/8/92	2-320	Damaske	5/15/92
410	Brook	4/28/92	410	Johnson	5/14/92	410	Russell	5/30/92
410	Mitch	4/28/92	342	Bowen	5/14/92	400	D. West	5-22-92

bcc: HFZ-401
HFZ-403
HFZ-410
D.O.

d/t: SXN: 042492

f/t: HFZ-410: SXN: smm: 042792

6



Memorandum

Date

From Jessica S. Lewis, Clerk-Typist (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K900070

To Division Director Philip Phillips

The attached information has been received by the 510(K) Document Mail Center (DMC), on the above referenced 510(K) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the document(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 427-1027. Thank you for your cooperation.

- Information does not change status of 510(K); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.
- Additional information requires a new 510(K); please process.

Comments:

↘ This revision letter ~~clarifies~~ specifies the limitations on the intended uses.
 ↘ See memo dated 4/22/92.
 ↘ Add copy of letter to file.

This information should be returned by _____.

Reviewed by:

SKN & SPR *SPR*

Panel:

Date:

ORDB _____

Attachment

*MXM
action slip for ORDB*

7

510K MEMO

FROM: SAMIE NIVER

SUBJECT: K900070, DYONICS PERCUTANEOUS A.M.D. SYSTEM

DATE: 4/22/92

ODE/DGRD/ADOR/ORDB

ADD TO 510(K) K900070:

On 2/16/92⁹⁰, a straight SE letter was sent to Dyonics instead of a modified SE letter limiting the indications for use of the Video Discoscope Set to visualization of lumbar herniated discs with placement of the scope under fluoroscopic support.

Depending on the specific indications for use, a spinal scope application may require clinical data in support of a SE decision. Therefore, Orthopedics feels that it is necessary to send a revised letter to the applicant specifying the exact indications for which it was found SE and all labeling limitations that are applicable.

A revised decision letter will be sent specifying the indications for use reflected above. A copy of the final letter should be added to the file.

8

Document Separator

Smith & Nephew Dyonics Inc.

160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: (508) 470-2800 Toll Free: 1-800-343-8386
Fax: (508) 470-2227

Smith+Nephew

June 28, 1994

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

Re : Transfer of 510(k) Ownership

Dear Madam/Sir :

This letter serves as formal notification to FDA of the transfer of ownership of the AMD™ System to Smith & Nephew Spine, a Division of Smith & Nephew Richards, Inc. This transaction includes the transfer of the following 510(k) notifications currently assigned to :

Smith & Nephew Dyonics, Inc.
160 Dascomb Road
Andover, MA 01810
Establishment Registration Number : 1216828

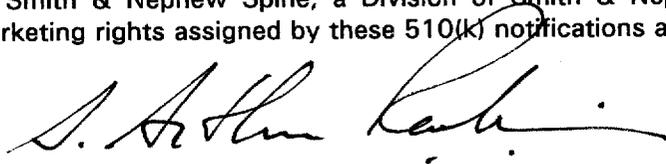
510(k) # K900070, Percutaneous Arthroscopic MicroDiscectomy System
510(k) # K922519, Bilateral Biportal AMD™ System
for Arthroscopic MicroDiscectomy

Transfer to :

Smith & Nephew Spine, a Division of Smith & Nephew Richards, Inc.
1450 Brooks Road
Memphis, TN 38116
Establishment Registration Number : 1020279

Effective July 1, 1994, Smith & Nephew Dyonics, Inc. will cease the marketing of these products and Smith & Nephew Spine, a Division of Smith & Nephew Richards, Inc. will assume all marketing rights assigned by these 510(k) notifications as approved.

Sincerely,



A. Arthur Rankis
Director R.A./Q.A.

cc : Jeff Cobb, Smith & Nephew Spine

RECEIVED
5 JUL 94 06 19
FDA/CDRH/ODE/DIVC

Document Separator



OCT 10 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. JoAnn Kuhne
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Re: K884263
Rogozinski Spinal Rod System

K896106
Rogozinski Spinal Rod System

K930298
Rogozinski Spinal Rod System

K950865
Rogozinski Rod-to-Bolt Connector

K954696
Rogozinski "Low Profile" Components (Empower)

K965224
Thoracolumbar Spinal Rod System (Empower)
Anterolateral Indications

K930480
Variable Angular Hold Bone Plate System (Amend)

K951389
ReUnion Bone Screw Titanium

K924141
SecureStrand Orthopaedic Polyethylene Cable

K943523
ALINE Anterior Cervical Plating System

K810234
Spinal Rod (L-Rod)

K970635
Titanium Spinal Rod System

K900070
AMD - Percutaneous Arthroscopic Microdiscectomy

K922519
AMD - Biportal Bilateral

|

Page 2 - Ms. Kuhne

K940222
SNS Deflecting Forceps

K950093
AMD Working Channel Scope and Accessories

Dear Ms. Kuhne:

We have reviewed your letter, dated October 6, 1997, stating that the rights to the above referenced premarket notifications (510(k)s) have been transferred. Your letter does not provide adequate information upon which we can base a decision to alter our database and change the name of the 510(k) submitter. Transfer of 510(k) rights alone does not require submission of a new 510(k) under 21 CFR 807.81(a)(3). Information showing the transfer of the 510(k)s and their current ownership should be maintained in your files for review by an FDA investigator. You may contact the Center for Devices and Radiological Health's Office of Compliance at (301) 594-4692 if you have any questions on what information we expect to be maintained in your files.

If you have any other questions regarding this letter, please contact the 510(k) Staff at (301) 594-1190.

Sincerely yours,



Heather S. Rosecrans
Chief, Premarket Notification
Section
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 10/8/97

From: Document Mail Center (HIFZ-401)

Subject: Premarket Notification Number(s) K9400070/A'

To: Division Director, CD/DGAD

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. Since a final decision has been rendered, this record is officially closed

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

_____ Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TRANSFER OF OWNERSHIP, PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS].

_____ Additional information requires a new 510(k), however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

_____ Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement)

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by _____

Date _____

K900070/A'

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

October 6, 1997

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

RECEIVED
OCT 9 11 09 AM '97
FDA/CDRH/ODE/OHC

Dear Sir or Madam:

Smith & Nephew, Inc., Orthopaedic Division, has transferred ownership of the following 510(k)s to United States Surgical Corporation (USSC).

Description	510(k) No.	Clearance Date
Rogozinski Spinal Rod System	K884263	12/29/88
Rogozinski Spinal Rod System	K896106	06/25/90
Rogozinski Spinal Rod System	K930298	06/14/95
Rogozinski Rod-to-Bolt Connector	K950865	09/01/95
Rogozinski "Low Profile" Components (Empower)	K954696	03/11/96
Thoracolumbar Spinal Rod System (Empower) - Anterolateral Indications	K965224	05/08/97
Variable Angular Hold Bone Plate System (AMEND)	K930480	06/15/94
ReUnion Bone Screw Titanium	K951389	07/24/95
SecureStrand Orthopaedic Polyethylene Cable	K924141	11/30/93
ALINE Anterior Cervical Plating System	K943523	12/19/94
Spinal Rod (L-Rod)	K810234	03/13/81
Titanium Spinal Rod System	K970635	08/14/97
AMD -Percutaneous Arthroscopic Microdiscectomy	K900070	05/22/92
AMD -Biportal Bilateral	K922519	03/29/94
SNS Deflecting Forceps	K940222	06/29/94
AMD Working Channel Scope and Accessories	K950093	08/15/95

Please address any future FDA correspondence regarding these 510(k)s to USSC.

Thank you for your attention to this matter and please don't hesitate to contact me if you have any questions regarding this transaction.

Sincerely,

JoAnn Kuhne
Manager, Regulatory Affairs

JK/es

cc: Sharon Murphy - USSC

SK-27 4