



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K974018 - 123 pages
COMPANY: WILSON-COOK MEDICAL, INC. (WILSCOOKMEDI)
PRODUCT: LIGATOR, HEMORRHOIDAL (FHN)
SUMMARY: Product: WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

DATE REQUESTED: Jun 7, 2016

DATE PRINTED: Jun 7, 2016

Note: Printed



RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 20 1998

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook 10 Shot Multi-Band Ligator consists of a friction fit adapter for attachment to the distal tip of an endoscope, a barrel preloaded with ten (10) ligation bands, a trigger cord and handle for band deployment, an irrigation adapter and a loading catheter. This device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The multi-band feature allows for serial ligations, which reduces the need to remove the endoscope for reloading. This device is supplied non-sterile and is intended for single use only.

Trade Name: Wilson-Cook Ten Shot Multi-Band Ligator

Common/Usual Name: Band Ligator

Classification Name/Code: Ligator, Hemorrhoidal, 78 FHN
Ligator, Esophageal 78 MND

Classification: FDA has classified similar devices as Class II, as per 21 CFR § 876.4400. This device falls within the purview of the Gastroenterology and Urology Device Panel.

Performance Standards: To the best of our knowledge, performance standards for this device do not exist.

Intended Use: Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Wilson-Cook Six Shot Multi-Band Ligator	Wilson-Cook Medical Inc.	K944220/A

Substantial Equivalence:
The Wilson-Cook 10 Shot Multi-Band Ligator is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	Wilson-Cook 10 Shot Multi-Band Ligator [Subject of 510(K)]	Wilson-Cook Multi-Band Ligator (K944220/A)
Intended Use	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.
Components	1) Non-Patient Contacting Loading Catheter 2) Irrigation Adapter 3) Barrel with 10 Ligation Bands 4) Trigger Cord 5) Deployment Handle	1) Non-Patient Contacting Loading Catheter 2) Irrigation Adapter 3) Barrel with 6 Ligation Bands 4) Trigger Cord 5) Deployment Handle
Patient Contacting Materials	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber
Method of Use	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.
Bands	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.
Sterility	Non-Sterile, Disposable	Non-Sterile, Disposable

Testing: Biocompatibility has been established for the patient contacting materials through a history of use in other similar medical devices and as applicable biocompatibility test results. This product line has been subjected to functional testing as appropriate for this modification. All results were comparable to results obtained for the predicate device hence establishing the safety and effectiveness for this product line extension.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Ms. Paula Joyce
Regulatory Affairs Manager
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K974018
Wilson-Cook 10 Shot Multi-band Ligator
Dated: October 17, 1997
Received: October 22, 1997
Regulatory Class: II
21 CFR 876.4400/Procode: 78 FHN, 78 MND

Dear Ms. Joyce:

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 (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

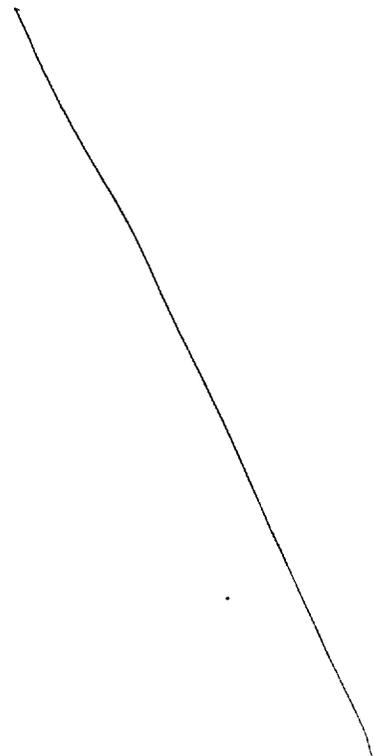
Enclosure

510(k) Number (if known): INITIAL 510(K) SUBMISSION UNKNOWN

Device Name: WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

Indications For Use:

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.



(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daker D. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974018

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Ms. Paula Joyce
Regulatory Affairs Manager
Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K974018
Wilson-Cook 10 Shot Multi-band Ligator
Dated: October 17, 1997
Received: October 22, 1997
Regulatory Class: II
21 CFR 876.4400/Procode: 78 FHN, 78 MND

Dear Ms. Joyce:

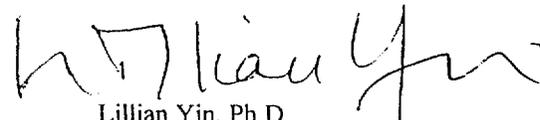
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

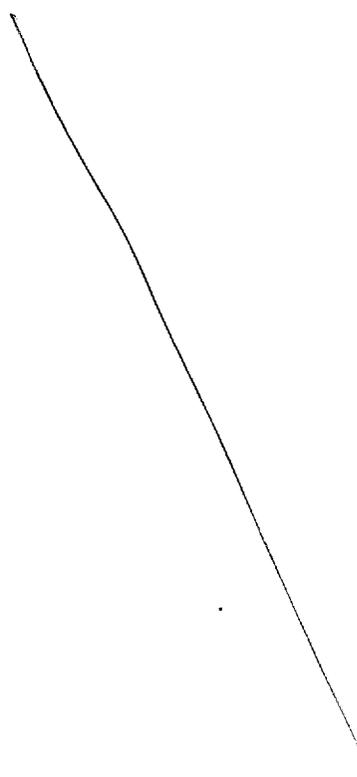
K974018

510(k) Number (if known): INITIAL 510(K) SUBMISSION UNKNOWN

Device Name: WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

Indications For Use:

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.



(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K97 4018

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

1/12/98

Memorandum

From: Reviewer(s) - Name(s) Jeffrey Cooper

Subject: 510(k) Number 15974018

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 10/29/97
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?

YES NO

Is this device subject to the Tracking Regulation?

YES NO

Was clinical data necessary to support the review of this 510(k)?

YES NO

Is this a prescription device?

YES NO

Was this 510(k) reviewed by a Third Party?

YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required W/A certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: 21 CFR 876.4400 Class II 78 FHW, 78 MND Additional Product Code(s) with panel (optional):

Review: Carolyn Y Newland, Ph.D GRDB 1/16/98
(Branch Chief) (Branch Code) (Date)

Final Review: D. Matting / J. Lin 1/20/98
(Division Director) (Date)

K974018 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

Reviewer: Jeffrey Cooper, M.S., D.V.M. **Division/Branch:** DRAERD/GRDB, HFZ-470

Trade Name: Wilson-Cook 10 Shot Multi-Band Ligator **510(k) Number:** K974018

Common Name: Hemorrhoidal Ligator and Esophageal Ligator.

Classification: 21 CFR § 876.4400, Class II, ProCode 78 FHN Hemorrhoidal Ligator, and Unclassified, ProCode 78 MND, Esophageal Ligator.

Date: January 12, 1998

Product To Which Compared: Wilson-Cook Six Shot Multi-Band Ligator (K944220).

Contact: Paula Joyce, Regulatory Affairs Manager

Phone: (910) 744-0157

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

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

5

Explanations to the Preceding Checklist:

7. The device has been modified from a three-string trigger cord to a two-string design. Also, four extra bands were added to the viewing area of the endoscope.

11. Performance data demonstrate equivalent forces are required to deploy the bands on the predicate device and the proposed device, and the viewing area of the proposed device is equivalent to the predicate device's viewing area.

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE:

The device is intended to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids. This device is supplied non-sterile and is intended for single use only.

2. DEVICE DESCRIPTION:

The proposed device is a modification of the predicate device. The Six Shot uses 6 bands. The Ten Shot uses 10 latex bands preloaded on a polycarbonate barrel with a friction fit adapter for attachment to the distal tip of an endoscope. Also included are a trigger cord and handle for band deployment, an irrigation adapter, and a loading catheter. The device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached, the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The device is non-sterile.

(b) (4) [Redacted]

Labeling has been provided which includes adequate instructions for use and package labeling. The package labeling includes a latex warning, the company name and address, the specifications required for the endoscope, a non-sterile statement, an expiration date, for single use, and an appropriate prescription statement as required by CFR 21.807.87 (e).

In compliance with the SMDA of 1990, the sponsor has included a summary of safety and effectiveness information.

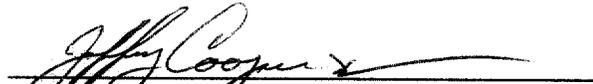
As long this product is manufactured under GMP's, it should be as safe and effective for its intended use as other similar legally marketed devices.

6

Life-supporting or life sustaining:	NO
Implant (short or long term):	NO
Software driven:	NO
Sterile:	NO
Patient Contacting Device:	YES
Single Use:	YES
Home Use:	NO
Prescription Use:	YES
Drug or Biological Product:	NO
Kit	NO

Recommendation:

I recommend that this device be found substantially equivalent to other legally marketed devices as described in 21 CFR § 876.4400, Class II, ProCode 78 FHN Hemorrhoidal Ligator, and Unclassified, ProCode 78 MND, Esophageal Ligator.


Jeffrey Cooper, M.S., D.V.M.
Gastroenterology and Renal Devices Branch

C. Neuland
1/16/98

MEMORANDUM

**Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
DRAERD/ADOU/GRDB**

Date: December 30, 1997

From: Jeffrey Cooper, M.S., D.V.M.
Gastroenterology and Renal Devices Branch, HFZ-470

Subject: **K974018 Wilson-Cook 10 Shot Multi-Band Ligator**

Company: Wilson-Cook Medical, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Contact: Paula Joyce, Regulatory Affairs Manager **Phone:** (910) 744-0157

To: The Record

Background:

Wilson-Cook Medical, Inc. has submitted a premarket notification for the Wilson-Cook 10 Shot Multi-Band Ligator. The notice is for a modification of a previous device.

Intended Use:

The device is intended to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids. This device is supplied non-sterile and is intended for single use only.

Predicate Device:

Wilson-Cook Six Shot Multi-Band Ligator (K944220).

General Information Summary:

The proposed device is a modification of the predicate device. The Six Shot uses 6 bands. The Ten Shot uses 10 latex bands preloaded on a polycarbonate barrel with a friction fit adapter for attachment to the distal tip of an endoscope. Also included are a trigger cord and handle for band deployment, an irrigation adapter, and a loading catheter. The device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached, the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The device is non-sterile.

(b) (4)



8

(b)
(4)

Life-supporting or life sustaining:	NO
Implant (short or long term):	NO
Software driven:	NO
Sterile:	NO
Patient Contacting Device:	YES
Single Use:	YES
Home Use:	NO
Prescription Use:	YES
Drug or Biological Product:	NO
Kit	NO

Submission Provides:

Comparative Specifications:	YES
Comparative Laboratory Data	YES
Summary of Animal Testing:	NO
Summary of Clinical Testing:	NO
510(k) Statement:	NO
510(k) Summary:	YES
Truthful and Accurate Statement:	YES
Indications for Use Statement:	YES

Sterilization:

The proposed device is provided non-sterile.

Pyrogen Testing:

Not applicable.

Biocompatibility:

The materials are identical to the predicates' except the polycarbonate is now obtained from a different supplier.

Biocompatibility testing included acceptable results of the following tests:

- Acute Systemic Toxicity
- Intracutaneous Toxicity
- Implantation 7 days
- Cytotoxicity Tissue Cell Culture MEM
- Direct Hemolysis
- Heavy metal analysis

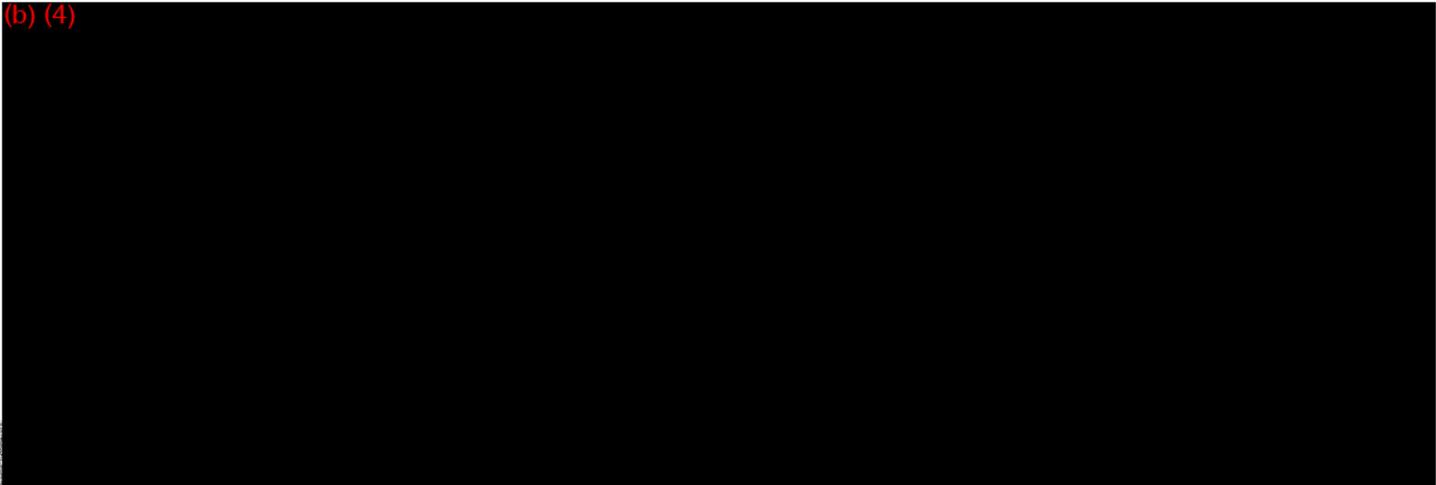
9

Labeling:

The labeling for the proposed device consists of adequate instructions for use and package labeling. The package labeling includes a prescription caution, a latex warning, the company name and address, the specifications required for the endoscope, a non-sterile statement, and an expiration date.

The expiration date is one year after the manufacturing date, based on bench top testing by the vendor showing the optimal life of the latex band in its stretched state.

Bench Testing:



Substantial Equivalence:

Indications for Use: Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

Device Design: The proposed device is similar to the predicate device. Adequate testing has been done to demonstrate equivalence.

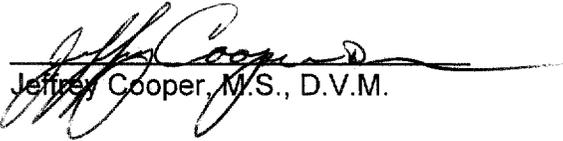
Proposed Classification:

21 CFR §876.4400, Class II, ProCode 78 FHN, Ligator, Hemorrhoidal, and Unclassified, 78 MND, Ligator, Esophageal.

10

Recommendation:

I recommend that this device be found substantially equivalent to other legally marketed devices as described in 21 CFR § 876.4400, Class II, ProCode 78 FHN Hemorrhoidal Ligator, and Unclassified, ProCode 78 MND, Esophageal Ligator.


Jeffrey Cooper, M.S., D.V.M.

C. Neuland
1/16/98



WILSON-COOK®
MEDICAL INC.
A COOK GROUP COMPANY

R974018/A1
FDA/CDRH/ODE/DMC

12 JAN 98 09 36

RECEIVED

January 8, 1998

Mr. Jeff Cooper
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

**RE: Additional Information for Wilson-Cook 10 Shot Multi-Band Ligator,
K974018**

Dear Mr. Cooper:

As per our phone conversation on January 7th, enclosed is the requested additional information for K974018. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Paula Joyce
Regulatory Affairs Manager

4900 Bethania Station Road

Winston-Salem, NC 27105

(910) 744-0157

Customer Service: (800) 245-4717

Office: (800) 245-4707

Fax: (910) 744-1147

SK-7

12

**RE: Additional Information for Wilson-Cook 10 Shot Multi-Band Ligator,
K974018**

Question # 1

Please provide additional information on the expiration date, which was referenced, on the package label.

Response # 1

Multi-Band Ligator Shelf-Life

The expiration date for this non-sterile product line is included on each package label and is based upon the life of its most limiting component, which is the latex ligation band. Bench-top testing for this product line showed that the optimal life of the latex band in its stretched state (i.e. placed on the barrel component) was one year. Therefore, the expiration date included on each package label is one year past the date of manufacture.

4900 Bethania Station Road
Winston-Salem, NC 27105
Phone: (336) 744-0157
Fax: (336) 767-2657



Fax

To: Mr. Jeff Cooper – FDA ODE **From:** Paula Joyce

Fax: (301) 594-2339 **Date:** January 8, 1998

Phone: **Pages:** 1

Re: Additional Information for 10 Shot **CC:**

Multi-Band Ligator, K974018

Urgent For Review Please Comment Please Reply Please Recycle

•Comments:

Dear Mr. Cooper:

As per our phone conversation on January 7th, the following is submitted in response to your concerns regarding the shelf life for our 10 Shot Multi-Band Ligator product line, which is the subject of K974018.

Multi-Band Ligator Shelf-Life

The expiration date for this non-sterile product line is included on each package label and is based upon the life of its most limiting component, which is the latex ligation band. Bench-top testing for this product line showed that the optimal life of the latex band in its stretched state (i.e. placed on the barrel component) was one year. Therefore, the expiration date included on each package label is one year past the date of manufacture.

This response will be sent under separate cover to the document mail center. Should you have any additional questions, please do not hesitate to contact me.

Sincerely,

Paula Joyce

Regulatory Affairs Manager

1h

510(k) Number & Device Name K974018 Wilson-Cook 10 Shot Multi-band Ligator

Company Wilson-Cook Medical, Inc.

ITEM	PRESENT		NEEDED (Y/N/?)
	Yes	No	
1. General information (i.e., trade & classification name, Est. Reg. No., device class, meets special controls or a performance standards, etc.)	<u>✓</u>	—	—
Reason for 510(k) - new device or modification	<u>✓</u>	—	—
Identification of legally marketed equivalent device	<u>✓</u>	—	—
Truthful and accurate statement	<u>✓</u>	—	—
SMDA 510(k) <u>summary</u> or statement	<u>✓</u>	—	—
2. Proposed Labeling, Labels, Advertisements	<u>✓</u>	—	—
Description of new device/modification	<u>✓</u>	—	—
Intended use statement	<u>✓</u>	—	—
Diagrams, Engineering Drawings, Photographs	<u>✓</u>	—	—
Indication for Use Statement	<u>✓</u>	—	—
3. Comparison of similarities/differences to named legally marketed equivalent device	<u>✓</u>	—	—
Equivalent Device Labeling, Labels, Advertising	<u>✓</u>	—	—
Intended use of equivalent device	<u>✓</u>	—	—
4. List of all patient contacting materials in new device	<u>✓</u>	—	—
Comparison of materials to equivalent device	<u>✓</u>	—	—
5. Biocompatibility information/data for patient contacting materials, OR	<u>✓</u>	—	—
Certification - identical material/formulation	<u>✓</u>	—	—
6. Performance data: Bench data	<u>✓</u>	—	—
Animal data	—	<u>✓</u>	<u>N</u>
Clinical data	—	<u>✓</u>	<u>N</u>
7. Sterilization information	—	<u>✓</u>	<u>N</u>
8. Software validation & verification	—	<u>✓</u>	<u>N</u>
9. If Class III, Class III Certification & Summary	—	<u>✓</u>	<u>N</u>
10. If kit, kit certification	—	<u>✓</u>	<u>N</u>

15

FOR REVIEWER'S USE ONLY

RRG 9/24/93
Rev. 5/8/95

DRAERD Premarket Notification 510(k)
SUPPLEMENTAL Screening Checklist

DRAERD has been given the go ahead to continue with the DRAERD Premarket Notification 510(k) Screening Checklist program rather than switching to the ODE Premarket Notification (510(k)) Checklist for Acceptance Decision. However, some items appear in the ODE Checklist that were not in the early version of the DRAERD Checklist or Explanation of the Checklist. Therefore, the following items should be included as part of the DRAERD screening process:

510(k) Number: K974018 TIER (Circle) II

Expedited Review Requested: N Granted: N OR, FDA Identified Expedited: N

ITEM	Yes	No
1. Is the product a device?	<u>✓</u>	—
2. Is the device exempt from 510(k) by regulation or policy?	—	<u>✓</u>
3. Are you aware that this device has been the subject of a previous NSE decision?	—	<u>✓</u>
If yes, does this new 510(k) address the NSE Issue(s) (e.g., performance data)?	—	<u>N/A</u>
4. Are you aware of the submitter being the subject of an integrity investigation?	—	<u>✓</u>
If yes, consult the ODE Integrity Officer, and has the ODE Integrity Officer given permission to proceed with the review?	—	<u>N/A</u>
5. Is there a specific guidance document for this device or device issue(s)?	—	<u>✓</u>
6. Is this a file that was determined to be substantially equivalent (SE) by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If yes, a new review by ODE is not required, please forward to POS.	—	<u>✓</u>

In addition, the following item is going to be required as part of a revision to the 510(k) regulation. However, it is not required now, but the Explanation of the DRAERD Screening Checklist has been modified to include this information.

7. Address of manufacturing facility/facilities, and if applicable, sterilization site(s). ✓ —

Administrative Reviewer Signature:  Date: 10/22/97

16

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

October 22, 1997

WILSON-COOK MEDICAL, INC.
4900 BETHANIA STATION RD.
& 5951 GRASSY CREEK BLVD.
WINSTON-SALEM, NC 27105
ATTN: PAULA JOYCE

510(k) Number: K974018
Received: 22-OCT-97
Product: WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

17



WILSON-COOK®
MEDICAL INC.
 A COOK GROUP COMPANY

11914-018
 K974018

RECEIVED
 OCT 22 10 07 AM '97
 FDA/CDRH/ODE/DMC

October 17, 1997

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

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
 MULTI-BAND LIGATOR**

Dear Sir or Madam:

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, that Wilson-Cook Medical Inc. intends to manufacture and market the Wilson-Cook 10 Shot Multi-Band Ligator. The following information is submitted pertaining to the Wilson-Cook 10 Shot Multi-Band Ligator:

1. **Classification Name/Code:** Ligator, Hemorrhoidal 78 FHN
 Ligator, Esophageal 78 MND
2. **Classification:** FDA has classified similar devices as Class II as per 21 CFR § 876.4400. This device falls within the purview of the Gastroenterology and Urology Device Panel.
3. **Trade Name/Proprietary Name:** Wilson-Cook 10 Shot Multi-Band Ligator
4. **Common/Usual Name:** Band Ligator

4900 Behavia Station Road
 Winston-Salem, NC 27105
 (910) 744-0157
 Customer Service: (800) 245-4717
 Office: (900) 245-4707
 Fax: (910) 744-1147

SK-14

10/22/97
 [Handwritten initials]

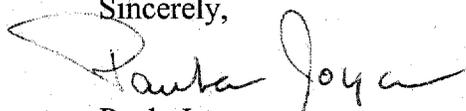
- 5. **Establishment Registration Number:** 1037905
- 6. No performance standards applicable to gastroenterology-urology ligation devices have been established by the Food and Drug Administration.
- 7. Package labeling and instructions for use are included as **Attachment I**.
- 8. This device is similar with respect to technological characteristics and intended use to predicate multi-band ligation devices, including the Wilson-Cook Multi-Band Ligator. Refer to **Table II** for a complete device comparison and to **Attachment II** for labeling and instructions for use for the referenced predicate device.

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Wilson-Cook Multiple Band Ligator	Wilson-Cook Medical Inc.	K944220/A

- 9. Refer to **Sections B through I** for information describing the Wilson-Cook 10 Shot Multi-Band Ligator.
- 10. The intended use statement is included in **Section A**.
- 11. The 510(k) Safety and Effectiveness Summary is included as **Section I** of this submission.
- 12. The Truthful and Accurate statement, as required by 21 CFR § 807.87(j) is included in **Section J** of this submission.

Wilson-Cook considers its' intent to manufacturer and market this product as confidential, commercial information, and we request that it be considered as such by FDA, and not be made available through Freedom of Information except where required by law. Should there be any questions pertaining to this submission, please do not hesitate to contact me.

Sincerely,



Paula Joyce
Regulatory Affairs Manager

Wilson-Cook Medical Inc.

Table of Contents for Ten Shot Multi Band Ligator

<u>Section/Title</u>	<u>Page(s)</u>
A. Intended Use	1
B. Physical Composition	2
C. Biocompatibility Data	2
D. Specifications	2-3
E. Sterilization	3
F. Method of Operation	3-4
G. Substantial Equivalence	4-7
H. Functional Testing	7-10
I. 510(K) Summary of Safety & Effectiveness	11-12
J. Truthful & Accurate Statement	13
Indications for Use Statement	14

Tables

Table I – Patient Contacting Materials	2
Table II – Substantial Equivalence Comparison	5
Table III – Endoscope Diameter Recommendation	7
Table IV – Results Summary for Force Applied to Trigger Cord	8
Table V – Endoscopic Field of Vision	9

20

Wilson-Cook Medical Inc.

Table of Contents for Ten Shot Multi Band Ligator

<u>Attachments</u>		<u>Section</u>
Attachment I	Package Labeling & Instructions for Use (10 Shot)	Attachment I
Attachment II	Package Labeling & Instructions for Use (Predicate Device)	Attachment II
Attachment III	Engineering Drawings Barrel Friction Fit Adapter/Barrel Assembly Trigger Cord Barrel with Bands/Friction Fit/Trigger Cord Assembly Deployment Handle Irrigation Adapter Loading Catheter	Attachment III
Attachment IV	Biocompatibility Data (Barrel)	Attachment IV
Attachment V	Engineering Drawing (Friction Fit/Barrel, Shoulder Reference)	Attachment V
Attachment VI	Endoscopic View when attached to Endoscope	Attachment VI

21

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

A. INTENDED USE

The Wilson-Cook Multi-Band Ligator is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids. This device is supplied non-sterile and is intended for single use only.

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

B. PHYSICAL COMPOSITION

The Wilson-Cook 10 Shot Multi-Band Ligator consists of a friction fit adapter; a barrel preloaded with 10 ligation bands, a trigger cord and handle. A loading catheter and irrigation adapter is also included with each ligator. Engineering drawings for all components are included as **Attachment III**. The patient contacting materials for all components are specified in **Table I**.

**TABLE I
MATERIALS OF CONSTRUCTION**

PATIENT CONTACTING COMPONENT	MATERIAL
(b) (4)	

C. BIOCOMPATIBILITY

Due to a vendor change for the barrel component raw material biocompatibility data equivalent to that submitted for the predicate device is included as **Attachment IV**.

Reasonable assurance of biocompatibility for the remaining materials listed by the above table is established by a history of use in the medical devices. It is hereby certified that identical materials are used in the referenced predicate device.

D. SPECIFICATIONS

Wilson-Cook Medical manufactures the Wilson-Cook 10 Multi-Band Ligator. Throughout manufacturing trained production and quality control inspectors follow standard operating procedures adhering to current Quality Systems Regulations providing reasonable assurance that the device will perform its intended function with safety and consistency. Specifications for this device are as per the following table:

23

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

D. SPECIFICATIONS (continued)

WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

Friction Fit Adapter (ID)	Barrel (ID)	Prestretched Band Diameter (ID)	Scope Size (Diameter)	Minimum Endoscope Channel Size	Endoscope Working Length
---------------------------	-------------	---------------------------------	-----------------------	--------------------------------	--------------------------

(b) (4)

E. STERILIZATION

The Wilson-Cook 10 Shot Multi-Band Ligator is a **non-sterile**, disposable device.

F. METHOD OF OPERATION

(b) (4)

27

RE: **PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

F. **METHOD OF OPERATION** (continued)

(b) (4)



G. **SUBSTANTIAL EQUIVALENCE**

The Wilson-Cook 10 Shot Multi-Band Ligator is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use. A complete comparison is included in **Table II**.

JS

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

G. SUBSTANTIAL EQUIVALENCE (continued)

TABLE II PRODUCT COMPARISON

DEVICE CHARACTERISTIC	Wilson-Cook 10 Shot Multi-Band Ligator [Subject of 510(K)]	Wilson-Cook Multi-Band Ligator (K944220/A)
Intended Use	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.
Components	1) Non-Patient Contacting Loading Catheter 2) Non-Patient Contacting Irrigation Adapter 3) Barrel with 10 Ligation Bands 4) Trigger Cord 5) Non-Patient Contacting Deployment Handle	1) Non-Patient Contacting Loading Catheter 2) Non-Patient Contacting Irrigation Adapter 3) Barrel with 6 Ligation Bands 4) Trigger Cord 5) Non-Patient Contacting Deployment Handle
Patient Contacting Materials	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber
Method of Use	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.
Bands	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.
Sterility	Non-Sterile, Disposable	Non-Sterile, Disposable

26

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

G. SUBSTANTIAL EQUIVALENCE (continued)

The Wilson-Cook 10 Shot Multi-Band Ligator differs slightly in design, as the barrel is preloaded with ten (10) bands as opposed to six (6) bands like the predicate device. This slight design modification has no impact on safety and effectiveness. In particular, there is no adverse impact on the endoscopic field of vision when the overall length of the barrel component is increased slightly to accommodate four additional bands.

**6 SHOT (PREDICATE) vs. 10 SHOT
Recommendations for Compatible Endoscope Diameters**

(b) (4)



27

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

G. SUBSTANTIAL EQUIVALENCE (continued)

Table III includes the slight dimensional differences between the Six and Ten Shot Devices and serves as further explanation of our rationale for endoscope diameter recommendations:

TABLE III

6 Shot Ligation Device (Predicate Device)	10 Shot Ligation Device [Subject of 510(k)]
(b) (4)	

H. FUNCTIONAL TESTING

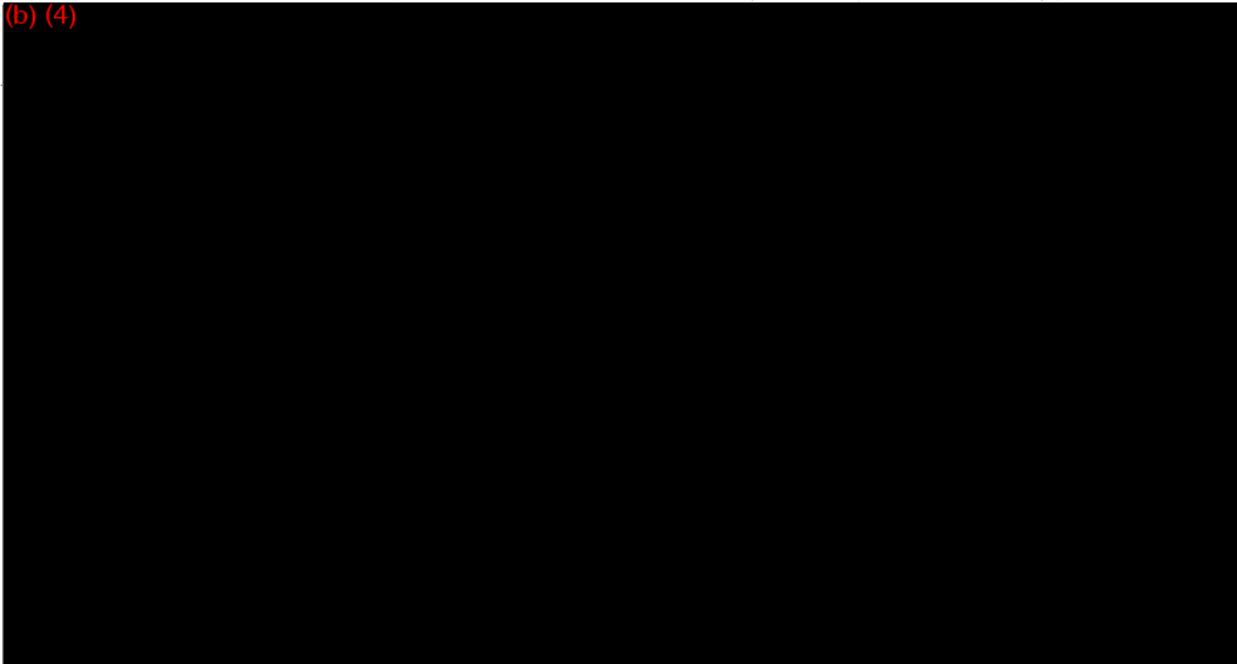
(b) (4)

28

RE: **PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

H. **FUNCTIONAL TESTING** (continued)

(b) (4)



**TABLE IV
RESULT SUMMARY FOR THE FORCE APPLIED TO TRIGGER CORD
TO DEPLOY BAND**

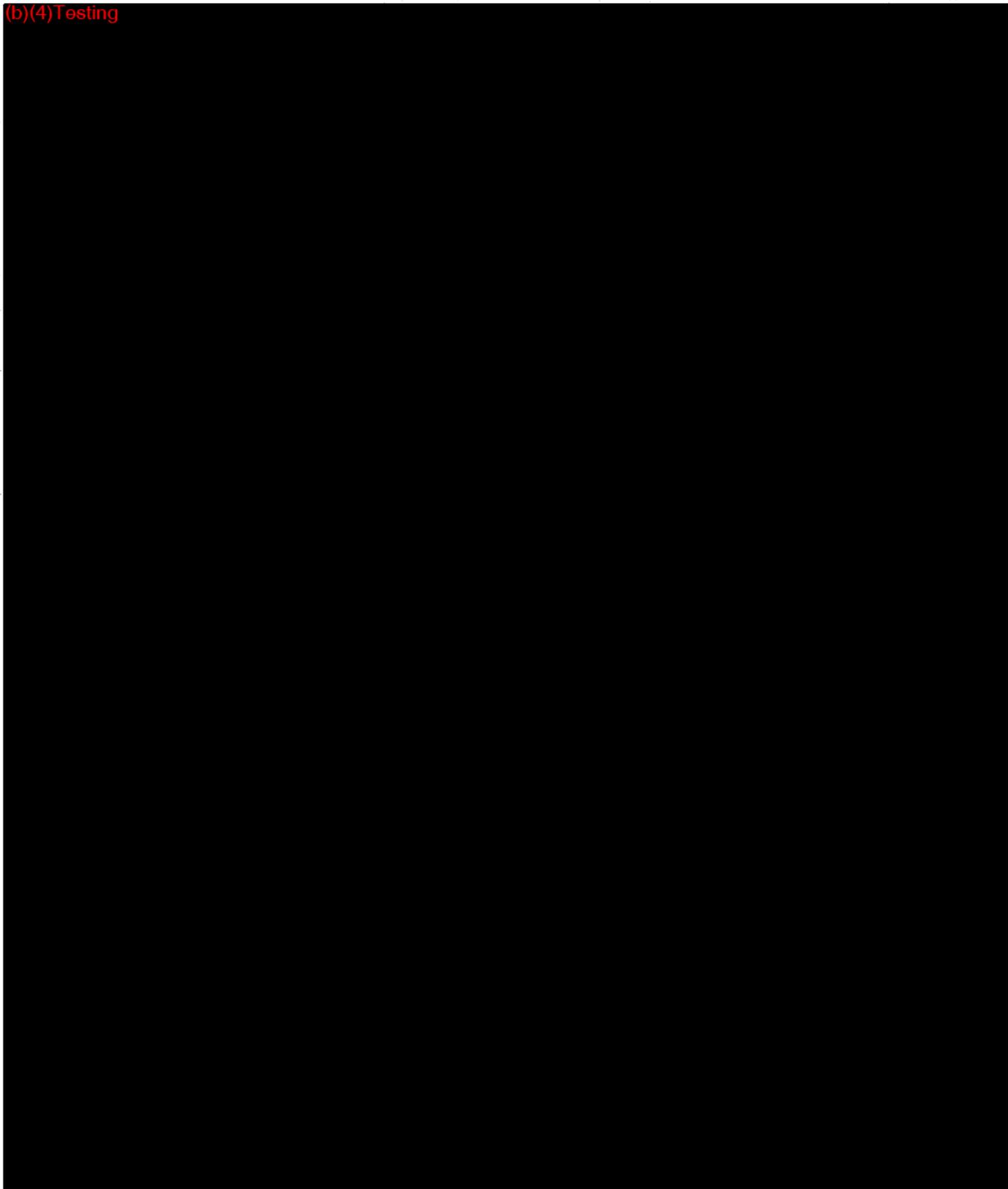
Three Stringed Trigger Cord Configuration	Two Stringed Trigger Cord Configuration
(b) (4)	

29

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

H. FUNCTIONAL TESTING (continued)

(b)(4) Testing

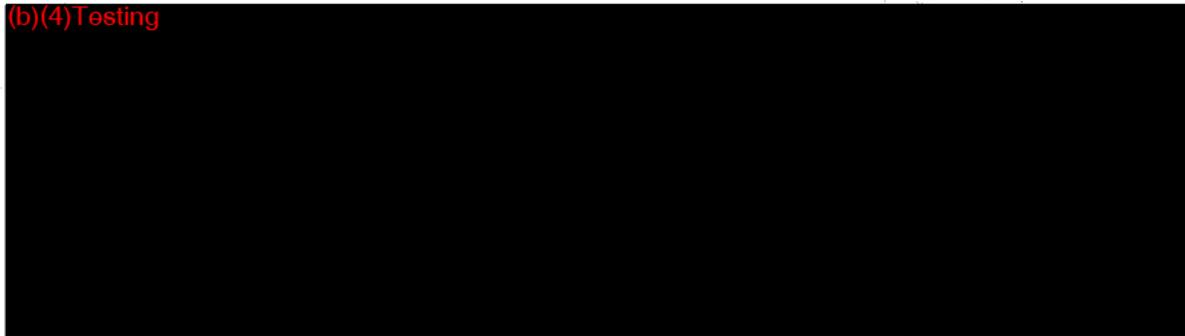


30

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

H. FUNCTIONAL TESTING (continued)

(b)(4) Testing



31

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Device Description:

The Wilson-Cook 10 Shot Multi-Band Ligator consists of a friction fit adapter for attachment to the distal tip of an endoscope, a barrel preloaded with ten (10) ligation bands, a trigger cord and handle for band deployment, an irrigation adapter and a loading catheter. This device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The multi-band feature allows for serial ligations, which reduces the need to remove the endoscope for reloading. This device is supplied non-sterile and is intended for single use only.

Trade Name: Wilson-Cook Ten Shot Multi-Band Ligator

Common/Usual Name: Band Ligator

Classification Name/Code: Ligator, Hemorrhoidal, 78 FHN
Ligator, Esophageal 78 MND

Classification: FDA has classified similar devices as Class II, as per 21 CFR § 876.4400. This device falls within the purview of the Gastroenterology and Urology Device Panel.

Performance Standards: To the best of our knowledge, performance standards for this device do not exist.

Intended Use: Used to endoscopically ligate esophageal varices at or above the gastroesophagal junction or to ligate internal hemorrhoids.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
Wilson-Cook Six Shot Multi-Band Ligator	Wilson-Cook Medical Inc.	K944220/A

Substantial Equivalence:

The Wilson-Cook 10 Shot Multi-Band Ligator is substantially equivalent to the referenced predicate device with respect to design, materials of construction and intended use.

32

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT MULTI-BAND LIGATOR

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	Wilson-Cook 10 Shot Multi-Band Ligator [Subject of 510(K)]	Wilson-Cook Multi-Band Ligator (K944220/A)
Intended Use	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.
Components	1) Non-Patient Contacting Loading Catheter 2) Irrigation Adapter 3) Barrel with 10 Ligation Bands 4) Trigger Cord 5) Deployment Handle	1) Non-Patient Contacting Loading Catheter 2) Irrigation Adapter 3) Barrel with 6 Ligation Bands 4) Trigger Cord 5) Deployment Handle
Patient Contacting Materials	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber	Friction Fit Adapter: Polyurethane Barrel: Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber
Method of Use	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.
Bands	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.	Multiple bands can perform serial ligations without removal of the endoscope for reloading of bands.
Sterility	Non-Sterile, Disposable	Non-Sterile, Disposable

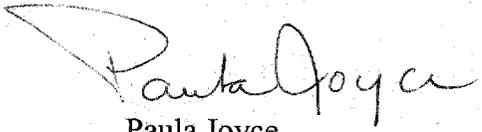
Testing: Biocompatibility has been established for the patient contacting materials through a history of use in other similar medical devices and as applicable biocompatibility test results. This product line has been subjected to functional testing as appropriate for this modification. All results were comparable to results obtained for the predicate device hence establishing the safety and effectiveness for this product line extension.

33

**RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK 10 SHOT
MULTI-BAND LIGATOR**

J. TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR § 807.87 (j)]

I certify that, in my capacity as the Regulatory Affairs Manager of Wilson-Cook Medical Inc., I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Paula Joyce

October 14, 1997

510(k) Number (if known): INITIAL 510(K) SUBMISSION UNKNOWN

Device Name: WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

Indications For Use:

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

35

**RECOMMENDED
ENDOSCOPE DIAMETER**

Multi-Band Ligator	Outer Diameter
4-Shooter	9.5 - 13 mm
6-Shooter	9.5 - 13 mm
10-Shooter	9.5 - 11.5 mm

CAUTION

Ensure the Opti-Vu™ barrel is advanced onto the tip of the endoscope as far as possible. Failure to do so may result in Opti-Vu barrel dislodgment.

NON-STERILE

**NICHT-STERIL
NON-STÉRILE
NO ESTÉRIL**

BATCH NUMBER
NUMÉRO DU GROUPE
GRUPPENUMMER
NUMERO DE LOTE

X X X

Patient Charge

Inventory

Patient Chart

MBL-10

TEN SHOOTER MULTI-BAND LIGATOR

BANDS PER LIGATOR: 10
 MINIMUM CHANNEL DIAMETER: 2.8 MM.
 ENDOSCOPE DIAMETER: 9.5 MM. - 11.5 MM.
 DISPOSABLE - SINGLE USE ONLY
 EXPIRATION DATE XX XXXX

NOTE: THIS PRODUCT HAS COMPONENTS THAT CONTAIN NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTIONS IN SOME INDIVIDUALS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Made in USA.

02/96

UPN



4900 Bethania Station Road • Winston-Salem, NC 27105

Description: TEN SHOOTER MULTI-BAND LIGATOR Lot No.: *XXX* Reorder No.: MBL-10	Description: TEN SHOOTER MULTI-BAND LIGATOR Lot No.: *XXX* Reorder No.: MBL-10	Description: TEN SHOOTER MULTI-BAND LIGATOR Lot No.: *XXX* Reorder No.: MBL-10
--	--	--

WILSON-COOK® WILSON-COOK® WILSON-COOK®

36

COPY

INTENDED USE

The Saeed Multi-Band Ligator is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids. This device is supplied non-sterile and is intended for single use only.



NOTES

To ensure these instructions are current, please contact Customer Service if the purchase date of this product has exceeded two years.

Do not use this device for any purpose other than the stated intended use.

If the product package is open or damaged when received, do not use this device.

Inventory rotation of this device is essential. Verify the expiration date on the package label. If the expiration date has lapsed, do not use this device.

Wilson-Cook devices should be stored in a dry location, away from temperature extremes.

CONTRAINDICATIONS

Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired banding site.

Contraindications specific to esophageal banding include, but are not limited to: cricopharyngeal or esophageal narrowing or stricture, tortuous

esophagus, diverticula, known or suspected esophageal perforation, asymptomatic rings or webs, coagulopathy.

Use of ligation bands is contraindicated in patients with a known hypersensitivity to latex.

POTENTIAL COMPLICATIONS

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

Additional complications which can occur with esophageal banding include, but are not limited to: retrosternal pain, nausea, laryngeal laceration, esophageal perforation, stricture formation, obstruction.

Hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

PRECAUTIONS

The coordination of endoscope accessory channel size with compatible devices is essential in obtaining optimal results during a procedure. The Multi-Band Ligator requires a minimum channel diameter of 2.8 mm and maximum accessory channel length of 122 cm.

The size requirements for the outer diameter of the endoscope are:

- Four Shooter: 9.5 mm - 13 mm

37

- Six Shooter: 9.5 mm - 13 mm
- Ten Shooter: 9.5 mm - 11.5 mm

Note: A diameter outside of this range is not compatible with the Opti-Vu™ barrel.

Band ligation may not be effective when applied to small varices.

CAUTIONS

A thorough understanding of the technical principles, clinical applications and risks associated with GI endoscopy and endoscopic banding is necessary before using this device. The Saeed Multi-Band Ligator should only be used by, or under the supervision of, physicians thoroughly trained in therapeutic endoscopy and vessel banding.

Esophageal ligation devices are not intended for ligation of varices below the gastroesophageal junction.

Current literature addresses the management of acutely bleeding esophageal varices and does not address the prophylactic use of banding.

Banding should begin at the gastroesophageal junction and proceed up the esophagus. Passing the endoscope over a previously placed band may dislodge the band.

Prior to assembling the Multi-Band Ligator, routine endoscopic examination is recommended to confirm the diagnosis requiring treatment of esophageal varices or internal hemorrhoids.

COMPONENT PARTS

Opti-Vu Barrel with preloaded Bands & attached Trigger Cord

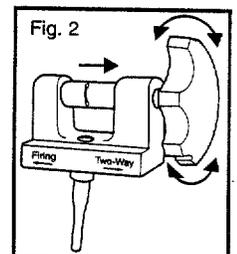
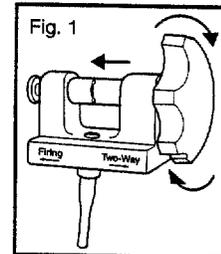
Multi-Band Ligator Handle

Loading Catheter

Irrigation Adapter

SYSTEM PREPARATION

1. Upon removal of the Saeed Multi-Band Ligator from the package, visually inspect the device with particular attention to kinks, bends or breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.
2. Examine the features of the Multi-Band Ligator handle. The handle has two positions which control rotation. The **firing** position (*fig. 1*) allows the handle to be rotated in the forward direction only. The **two-way** position (*fig. 2*) allows the handle to rotate in both directions. Prior to introducing the endoscope, keep the handle in the two-way position.

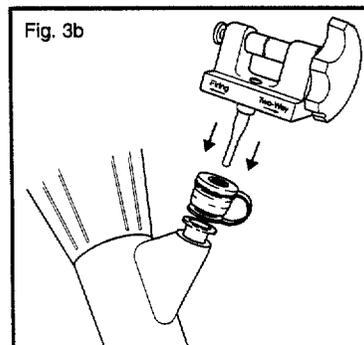
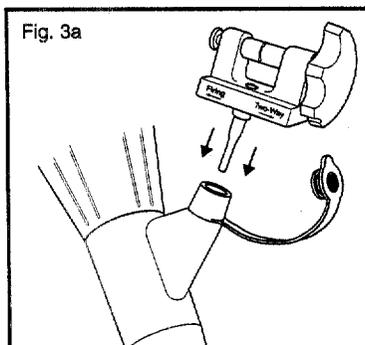


38

3. Insert the Multi-Band Ligator handle into the endoscope accessory channel following the instructions below for the appropriate endoscope.

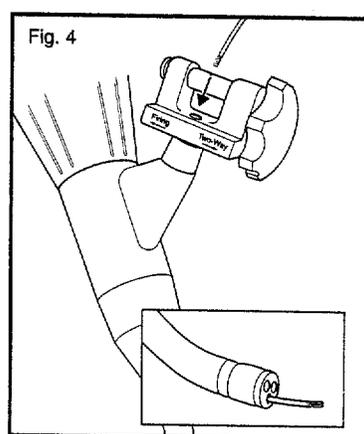
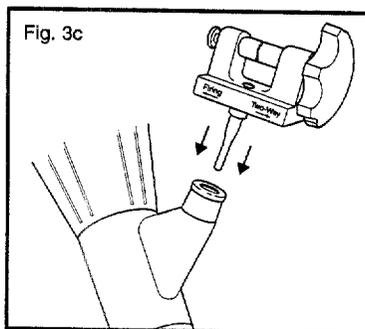
Olympus - With the rubber cap on the accessory channel, lift the plug on the cap and insert the stem of the Multi-Band Ligator handle. (fig. 3a)

Pentax - Remove the rubber cap from the accessory channel. Place the stem of the Multi-Band Ligator handle through the cap. Replace the cap and inserted handle, as a unit, onto the Luer lock fitting of the accessory channel. (fig. 3b)



Fujinon - Place the stem of the Multi-Band Ligator handle through the rubber cap attached to the endoscope accessory channel. (fig. 3c)

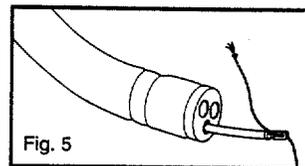
4. Introduce the loading catheter through the white seal in the Multi-Band



Ligator handle and advance, in short increments, until it exits the tip of the endoscope. (fig. 4)

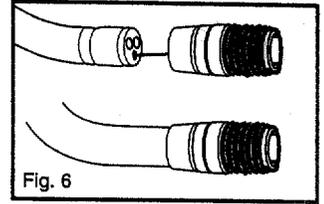
Note: The loading catheter is identical on both ends and may be introduced either way.

5. Attach the trigger cord to the hook on the end of the loading catheter, leaving approximately 2 cm of trigger cord between the knot and the hook. (fig. 5) Withdraw the loading catheter and trigger cord up through the endoscope and out through the Multi-Band Ligator handle. Dispose of the loading catheter per institutional guidelines for biohazardous medical waste.

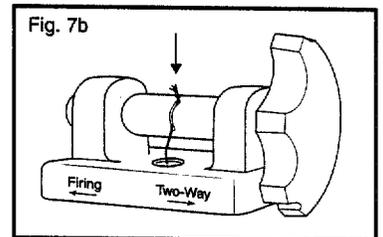
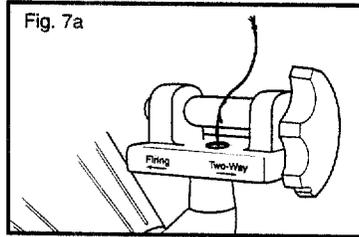


39

6. Attach the Opti-Vu barrel to the tip of the endoscope, ensuring the barrel is advanced onto the tip as far as possible. (fig. 6)



7. With the endoscope tip straight, place the trigger cord into the slot on the spool of the Multi-Band Ligator handle (fig. 7a) and pull down until the knot is seated in the hole of the slot. (fig. 7b) **Note:** The knot **must** be seated into the hole or the handle will not function properly.



8. With the Multi-Band Ligator handle in the two-way position, slowly rotate the handle clockwise to wind the trigger cord onto the handle spool until it is taut. (fig. 8) **Note:** Care must be taken to avoid deploying a band while winding the trigger cord.

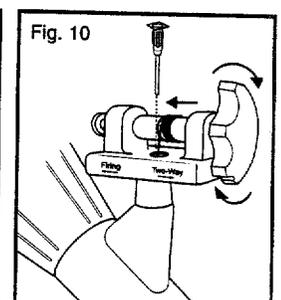
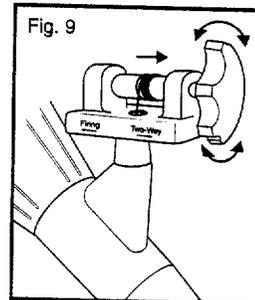
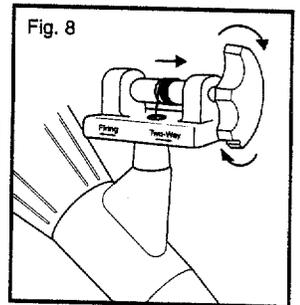
9. Check the endoscopic view. To maximize visualization, the position of the trigger cord may be altered by rotating the Opti-Vu barrel. **Note:** The endoscopic view broadens after each band deployment.

The Saeed Multi-Band Ligator is now ready for rapid ligation of esophageal varices or internal hemorrhoids.

INSTRUCTIONS FOR LIGATION OF ESOPHAGEAL VARICES

Note: Please see additional instructions below on how to ligate internal hemorrhoids.

1. Lubricate the endoscope and exterior portion of the Opti-Vu barrel. **Note:** Do not place lubricant inside the Opti-Vu barrel.
2. With the Multi-Band Ligator handle in the **two-way** position, introduce the endoscope into the esophagus. (fig. 9) After intubation, place the handle in the firing position. (fig. 10)
3. Visualize the selected varix and aspirate it into the Opti-Vu barrel. **Caution:** Prior to band deployment, ensure the endoscopist's hand is positioned on the



no

handle of the Multi-Band Ligator rather than the endoscope controls.

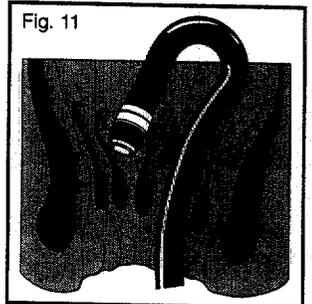
4. Maintain suction and deploy the band by rotating the Multi-Band Ligator handle clockwise until band release is **felt**, indicating deployment. (fig. 10) **Note:** If the band will not deploy, place the handle in the two-way position and loosen the trigger cord slightly. Place the handle in the firing position and continue with the procedure.
5. Release the suction button of the endoscope, insufflate air, then withdraw the scope slightly to release the ligated varix. **Note:** An irrigation adapter is provided with each Saeed Multi-Band Ligator. If irrigation of the endoscope accessory channel is desired to clear the viewing field, attach the adapter to a syringe filled with sterile water and insert into the white seal of the handle. Irrigate as necessary. (fig. 10)
6. Repeat the ligation process as needed. **Note:** More than one ligation band for each varix may be required to control acute bleeding.
7. If more bands are required, remove the endoscope and attach a new Saeed Multi-Band Ligator. **Note:** An average of 3 to 4 ligation sessions may be required to obliterate varices.

INSTRUCTIONS FOR LIGATION OF INTERNAL HEMORRHOIDS

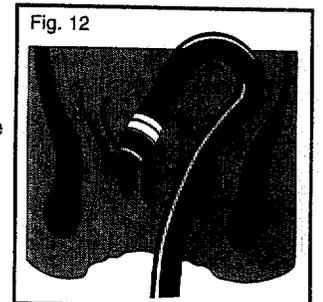
Note: A flexible sigmoidoscopic screening exam of the hemorrhoidal site must be performed prior to assembling and use of the Multi-Band Ligator.

1. Lubricate the endoscope and exterior portion of the Opti-Vu barrel. **Note:** Do not place lubricant inside the Opti-Vu barrel.
2. With the Multi-Band Ligator handle in the **two-way position**, introduce the endoscope into the rectum. (fig. 9)

3. Retroflex the endoscope to visualize the selected internal hemorrhoid. (fig. 11) After retroflexion, place the handle in the firing position (fig. 10), then aspirate the internal hemorrhoid into the Opti-Vu barrel. (fig. 12) **Caution:** Ligation should only be performed on internal hemorrhoids located above the dentate line. Treatment below the dentate line may result in pain. Prior to band deployment, ensure the endoscopist's hand is positioned on the handle of the Multi-Band Ligator rather than the endoscope controls.



4. Maintain suction of the internal hemorrhoid and deploy the band by rotating the Multi-Band Ligator handle clockwise until band release is **felt**, indicating deployment. (fig. 10) **Note:** If the band will not deploy, place the handle in the two-way position and loosen the trigger cord slightly. Place the handle in the



hl

firing position and continue with the procedure.

5. Release the suction button of the endoscope, insufflate air, then advance the scope slightly to release the ligated hemorrhoid.
Note: An irrigation adapter is provided with each Saeed Multi-Band Ligator. If irrigation of the endoscope accessory channel is desired to clear the viewing field, attach the adapter to a syringe filled with sterile water and insert into the white seal of the handle. Irrigate as necessary. (fig. 10)
6. Repeat the ligation process as needed.
7. Place the handle in the two-way position when the ligation process is completed, **then** straighten the scope.
8. If more bands are required, remove the endoscope and attach a new Saeed Multi-Band Ligator.

REMOVING THE MULTI-BAND LIGATOR

1. Upon completion of the ligation procedure, remove the endoscope from the patient.
2. Dismantle the Multi-Band Ligator as follows:
If all the bands have been fired:
 - Remove the handle and attached trigger cord from the accessory channel.

- Remove the Opti-Vu barrel from the endoscope tip.

If any unfired bands remain on the barrel:

- Place the handle in the two-way position.
 - Loosen the trigger cord from the spool, then remove the handle from the accessory channel cap.
 - Detach the trigger cord from the handle slot.
 - Remove the Opti-Vu barrel from the endoscope tip; then pull the trigger cord through the channel and out the endoscope tip.
3. Upon completion of the procedure, dispose of the devices per institutional guidelines for biohazardous medical waste.

THE LEARNING CONNECTION™



Reference Articles



Video

h2

ORDERING INFORMATION

Order No.	Description
MBL-4	Saeed 4-Shooter™ One complete kit includes: Opti-Vu Barrel with four pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-6	Saeed 6-Shooter™ One complete kit includes: Opti-Vu Barrel with six pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-10	Saeed 10-Shooter™ One complete kit includes: Opti-Vu Barrel with ten pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-36	Six Complete 6-Shooter Kits

Saeed 4-Shooter, Saeed 6-Shooter, Saeed 10-Shooter, Opti-Vu and The Learning Connection are trademarks of Wilson-Cook Medical Inc. Wilson-Cook is a registered trademarks of Wilson-Cook Medical Inc.

© 1997 Wilson-Cook Medical Inc.

h3

ATTACHMENT II

RE: PREMARKET NOTIFICATION FOR WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

Six Shot Multi-Band Ligator

Package Labeling

NON-STERILE

**NICHT-STERIL
NON-STÉRILE
NO ESTÉRIL**

BATCH NUMBER
NUMÉRO DU GROUPE
GRUPPENNUMMER
NUMERO DE LOTE

X X X

MBL-6

SIX SHOOTER MULTI-BAND LIGATOR

BANDS PER LIGATOR: 6
MINIMUM CHANNEL DIAMETER: 2.8 MM.
ENDOSCOPE DIAMETER: 9.5 MM. - 13 MM.
DISPOSABLE - SINGLE USE ONLY
EXPIRATION DATE XX XXXX

NOTE: THIS PRODUCT HAS COMPONENTS THAT CONTAIN
NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC
REACTIONS IN SOME INDIVIDUALS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of
a physician. Made in USA.

02/96



UPN

4900 Bethania Station Road • Winston-Salem, NC 27105

Patient Charge	Inventory	Patient Chart
<p>Reorder No.: MBL-6</p> <p>Lot No.: *XXX*</p> <p>Description: SIX SHOOTER MULTI-BAND LIGATOR</p>	<p>Reorder No.: MBL-6</p> <p>Lot No.: *XXX*</p> <p>Description: SIX SHOOTER MULTI-BAND LIGATOR</p>	<p>Reorder No.: MBL-6</p> <p>Lot No.: *XXX*</p> <p>Description: SIX SHOOTER MULTI-BAND LIGATOR</p>

WH

ATTACHMENT II

RE: PREMARKET NOTIFICATION FOR WILSON-COOK TEN SHOT MULTI-BAND LIGATOR

SIX SHOT MULTI-BAND LIAGTOR

PACKAGE LABELING

**RECOMMENDED
ENDOSCOPE DIAMETER**

Multi-Band Ligator	Outer Diameter
4-Shooter	9.5 - 13 mm
6-Shooter	9.5 - 13 mm
10-Shooter	9.5 - 11.5 mm

CAUTION

Ensure the Opti-Vu™ barrel is advanced onto the tip of the endoscope as far as possible. Failure to do so may result in Opti-Vu barrel dislodgment.

NS

COPY

INTENDED USE

The Saeed Multi-Band Ligator is used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids. This device is supplied non-sterile and is intended for single use only.



NOTES

To ensure these instructions are current, please contact Customer Service if the purchase date of this product has exceeded two years.

Do not use this device for any purpose other than the stated intended use.

If the product package is open or damaged when received, do not use this device.

Inventory rotation of this device is essential. Verify the expiration date on the package label. If the expiration date has lapsed, do not use this device.

Wilson-Cook devices should be stored in a dry location, away from temperature extremes.

CONTRAINDICATIONS

Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired banding site.

Contraindications specific to esophageal banding include, but are not limited to: cricopharyngeal or esophageal narrowing or stricture, tortuous

esophagus, diverticula, known or suspected esophageal perforation, asymptomatic rings or webs, coagulopathy.

Use of ligation bands is contraindicated in patients with a known hypersensitivity to latex.

POTENTIAL COMPLICATIONS

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

Additional complications which can occur with esophageal banding include, but are not limited to: retrosternal pain, nausea, laryngeal laceration, esophageal perforation, stricture formation, obstruction.

Hemorrhoidal banding may result in severe pain if the procedure is performed below the dentate line.

PRECAUTIONS

The coordination of endoscope accessory channel size with compatible devices is essential in obtaining optimal results during a procedure. The Multi-Band Ligator requires a minimum channel diameter of 2.8 mm and maximum accessory channel length of 122 cm.

The size requirements for the outer diameter of the endoscope are:

- Four Shooter: 9.5 mm - 13 mm

h6

- Six Shooter: 9.5 mm - 13 mm
- Ten Shooter: 9.5 mm - 11.5 mm

Note: A diameter outside of this range is not compatible with the Opti-Vu™ barrel.

Band ligation may not be effective when applied to small varices.

CAUTIONS

A thorough understanding of the technical principles, clinical applications and risks associated with GI endoscopy and endoscopic banding is necessary before using this device. The Saeed Multi-Band Ligator should only be used by, or under the supervision of, physicians thoroughly trained in therapeutic endoscopy and vessel banding.

Esophageal ligation devices are not intended for ligation of varices below the gastroesophageal junction.

Current literature addresses the management of acutely bleeding esophageal varices and does not address the prophylactic use of banding.

Banding should begin at the gastroesophageal junction and proceed up the esophagus. Passing the endoscope over a previously placed band may dislodge the band.

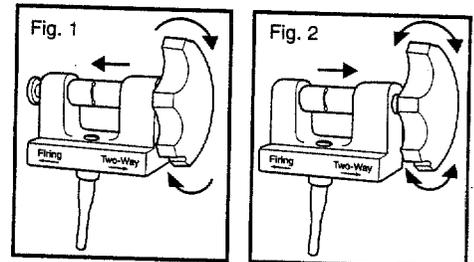
Prior to assembling the Multi-Band Ligator, routine endoscopic examination is recommended to confirm the diagnosis requiring treatment of esophageal varices or internal hemorrhoids.

COMPONENT PARTS

- Opti-Vu Barrel with preloaded Bands & attached Trigger Cord
- Multi-Band Ligator Handle
- Loading Catheter
- Irrigation Adapter

SYSTEM PREPARATION

1. Upon removal of the Saeed Multi-Band Ligator from the package, visually inspect the device with particular attention to kinks, bends or breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Wilson-Cook for return authorization.
2. Examine the features of the Multi-Band Ligator handle. The handle has two positions which control rotation. The **firing** position (*fig. 1*) allows the handle to be rotated in the forward direction only. The **two-way** position (*fig. 2*) allows the handle to rotate in both directions. Prior to introducing the endoscope, keep the handle in the two-way position.

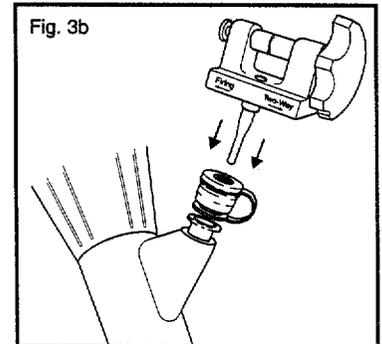
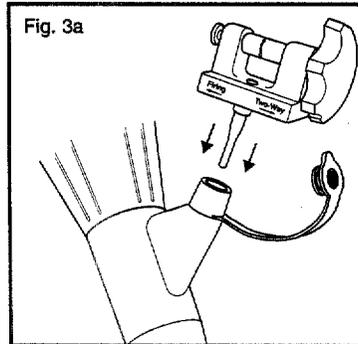


W7

3. Insert the Multi-Band Ligator handle into the endoscope accessory channel following the instructions below for the appropriate endoscope.

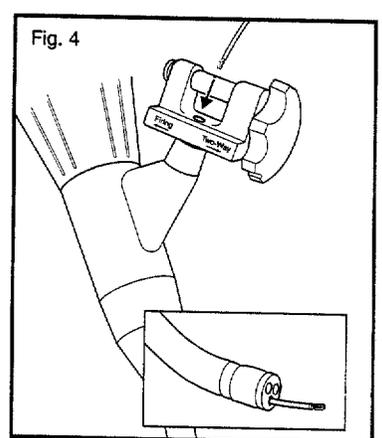
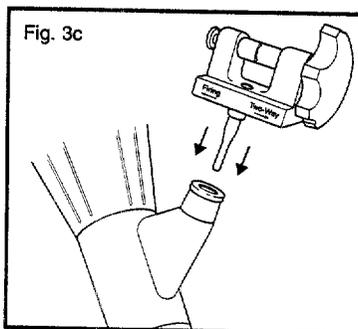
Olympus - With the rubber cap on the accessory channel, lift the plug on the cap and insert the stem of the Multi-Band Ligator handle. (fig. 3a)

Pentax - Remove the rubber cap from the accessory channel. Place the stem of the Multi-Band Ligator handle through the cap. Replace the cap and inserted handle, as a unit, onto the Luer lock fitting of the accessory channel. (fig. 3b)



Fujinon - Place the stem of the Multi-Band Ligator handle through the rubber cap attached to the endoscope accessory channel. (fig. 3c)

4. Introduce the loading catheter through the white seal in the Multi-Band Ligator handle.

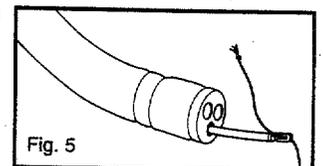


Ligator handle and advance, in short increments, until it exits the tip of the endoscope. (fig. 4)

Note: The loading catheter is identical on both ends and may be introduced either way.

5. Attach the trigger cord to the hook on the end of the loading catheter, leaving approximately 2 cm of trigger cord between the knot and the hook. (fig. 5) Withdraw the loading catheter and trigger cord up through the endoscope and out through the Multi-Band Ligator handle.

Dispose of the loading catheter per institutional guidelines for biohazardous medical waste.



h8

6. Attach the Opti-Vu barrel to the tip of the endoscope, ensuring the barrel is advanced onto the tip as far as possible. (fig. 6)

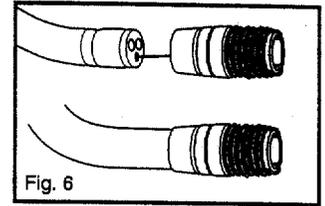


Fig. 6

7. With the endoscope tip straight, place the trigger cord into the slot on the spool of the Multi-Band Ligator handle (fig. 7a) and pull down until the knot is seated in the hole of the slot. (fig. 7b) **Note:** The knot **must** be seated into the hole or the handle will not function properly.

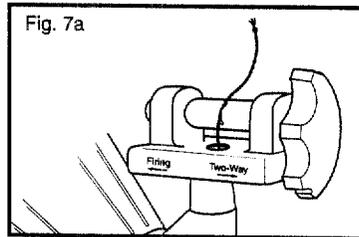


Fig. 7a

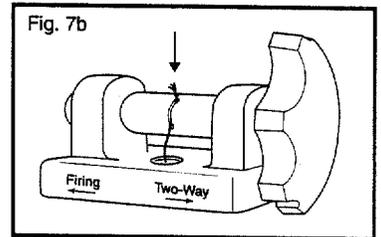


Fig. 7b

8. With the Multi-Band Ligator handle in the two-way position, slowly rotate the handle clockwise to wind the trigger cord onto the handle spool until it is taut. (fig. 8) **Note:** Care must be taken to avoid deploying a band while winding the trigger cord.

9. Check the endoscopic view. To maximize visualization, the position of the trigger cord may be altered by rotating the Opti-Vu barrel. **Note:** The endoscopic view broadens after each band deployment.

The Saeed Multi-Band Ligator is now ready for rapid ligation of esophageal varices or internal hemorrhoids.

INSTRUCTIONS FOR LIGATION OF ESOPHAGEAL VARICES

Note: Please see additional instructions below on how to ligate internal hemorrhoids.

1. Lubricate the endoscope and exterior portion of the Opti-Vu barrel. **Note:** Do not place lubricant inside the Opti-Vu barrel.
2. With the Multi-Band Ligator handle in the **two-way** position, introduce the endoscope into the esophagus. (fig. 9) After intubation, place the handle in the firing position. (fig. 10)
3. Visualize the selected varix and aspirate it into the Opti-Vu barrel. **Caution:** Prior to band deployment, ensure the endoscopist's hand is positioned on the

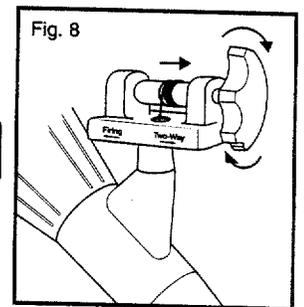


Fig. 8

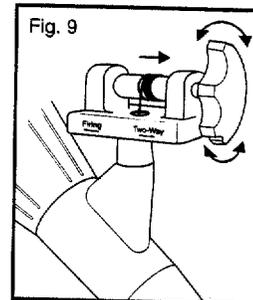


Fig. 9

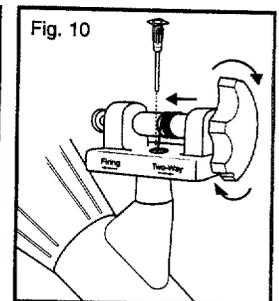


Fig. 10

W9

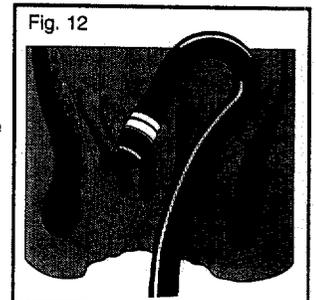
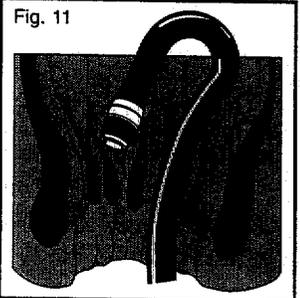
handle of the Multi-Band Ligator rather than the endoscope controls.

4. Maintain suction and deploy the band by rotating the Multi-Band Ligator handle clockwise until band release is **felt**, indicating deployment. (fig. 10) **Note:** If the band will not deploy, place the handle in the two-way position and loosen the trigger cord slightly. Place the handle in the firing position and continue with the procedure.
5. Release the suction button of the endoscope, insufflate air, then withdraw the scope slightly to release the ligated varix. **Note:** An irrigation adapter is provided with each Saeed Multi-Band Ligator. If irrigation of the endoscope accessory channel is desired to clear the viewing field, attach the adapter to a syringe filled with sterile water and insert into the white seal of the handle. Irrigate as necessary. (fig. 10)
6. Repeat the ligation process as needed. **Note:** More than one ligation band for each varix may be required to control acute bleeding.
7. If more bands are required, remove the endoscope and attach a new Saeed Multi-Band Ligator. **Note:** An average of 3 to 4 ligation sessions may be required to obliterate varices.

INSTRUCTIONS FOR LIGATION OF INTERNAL HEMORRHOIDS

Note: A flexible sigmoidoscopic screening exam of the hemorrhoidal site must be performed prior to assembling and use of the Multi-Band Ligator.

1. Lubricate the endoscope and exterior portion of the Opti-Vu barrel. **Note:** Do not place lubricant inside the Opti-Vu barrel.
2. With the Multi-Band Ligator handle in the **two-way position**, introduce the endoscope into the rectum. (fig. 9)
3. Retroflex the endoscope to visualize the selected internal hemorrhoid. (fig. 11) After retroflexion, place the handle in the firing position (fig. 10), then aspirate the internal hemorrhoid into the Opti-Vu barrel. (fig. 12) **Caution:** Ligation should only be performed on internal hemorrhoids located above the dentate line. Treatment below the dentate line may result in pain. Prior to band deployment, ensure the endoscopist's hand is positioned on the handle of the Multi-Band Ligator rather than the endoscope controls.
4. Maintain suction of the internal hemorrhoid and deploy the band by rotating the Multi-Band Ligator handle clockwise until band release is **felt**, indicating deployment. (fig. 10) **Note:** If the band will not deploy, place the handle in the two-way position and loosen the trigger cord slightly. Place the handle in the



firing position and continue with the procedure.

5. Release the suction button of the endoscope, insufflate air, then advance the scope slightly to release the ligated hemorrhoid.
Note: An irrigation adapter is provided with each Saeed Multi-Band Ligator. If irrigation of the endoscope accessory channel is desired to clear the viewing field, attach the adapter to a syringe filled with sterile water and insert into the white seal of the handle. Irrigate as necessary. (fig. 10)
6. Repeat the ligation process as needed.
7. Place the handle in the two-way position when the ligation process is completed, **then** straighten the scope.
8. If more bands are required, remove the endoscope and attach a new Saeed Multi-Band Ligator.

REMOVING THE MULTI-BAND LIGATOR

1. Upon completion of the ligation procedure, remove the endoscope from the patient.
2. Dismantle the Multi-Band Ligator as follows:
If all the bands have been fired:
 - Remove the handle and attached trigger cord from the accessory channel.

- Remove the Opti-Vu barrel from the endoscope tip.

If any unfired bands remain on the barrel:

- Place the handle in the two-way position.
 - Loosen the trigger cord from the spool, then remove the handle from the accessory channel cap.
 - Detach the trigger cord from the handle slot.
 - Remove the Opti-Vu barrel from the endoscope tip, then pull the trigger cord through the channel and out the endoscope tip.
3. Upon completion of the procedure, dispose of the devices per institutional guidelines for biohazardous medical waste.

THE LEARNING CONNECTION™



Reference Articles



Video

51

ORDERING INFORMATION

Order No.	Description
MBL-4	Saeed 4-Shooter™ One complete kit includes: Opti-Vu Barrel with four pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-6	Saeed 6-Shooter™ One complete kit includes: Opti-Vu Barrel with six pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-10	Saeed 10-Shooter™ One complete kit includes: Opti-Vu Barrel with ten pre-loaded bands & attached Trigger Cord, Multi-Band Ligator Handle, Loading Catheter and Irrigation Adapter.
MBL-36	Six Complete 6-Shooter Kits

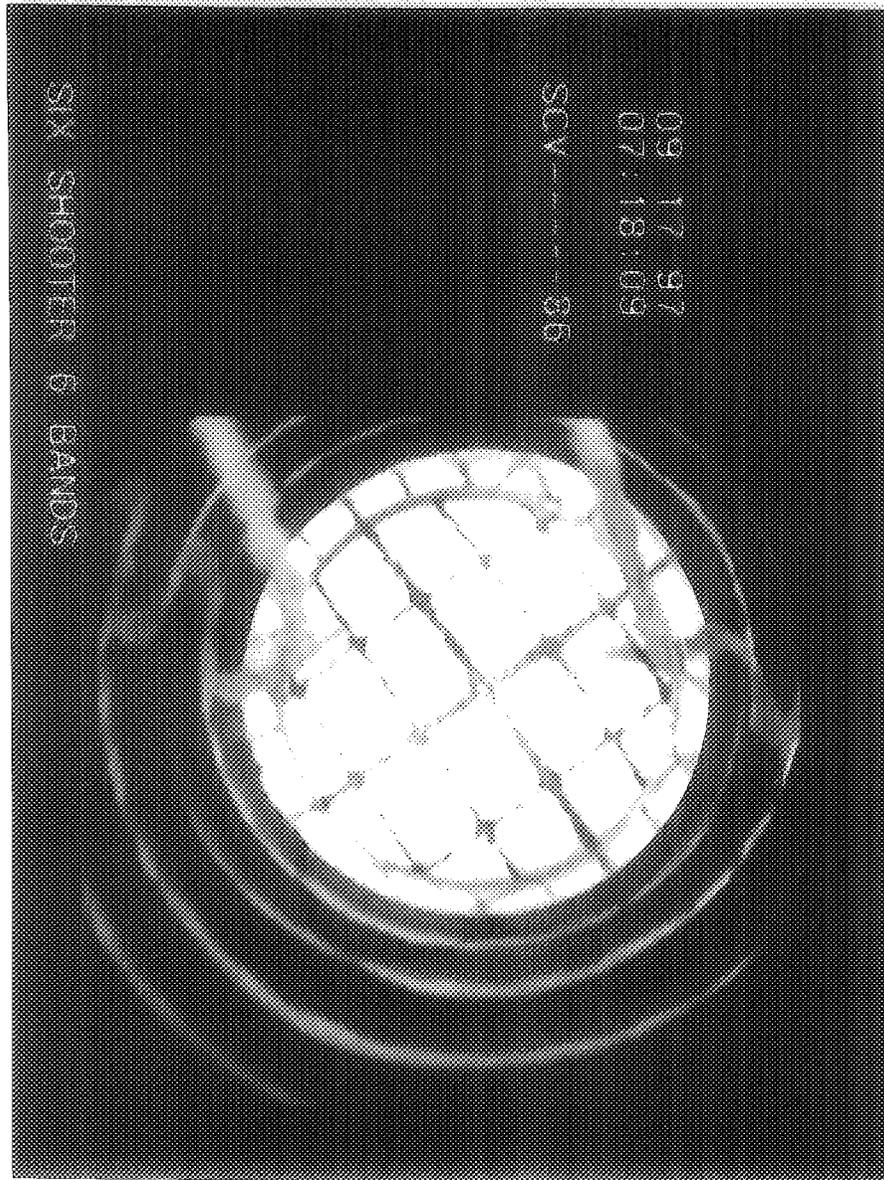
Saeed 4-Shooter, Saeed 6-Shooter, Saeed 10-Shooter, Opti-Vu and The Learning Connection are trademarks of Wilson-Cook Medical Inc. Wilson-Cook is a registered trademarks of Wilson-Cook Medical Inc.

© 1997 Wilson-Cook Medical Inc.

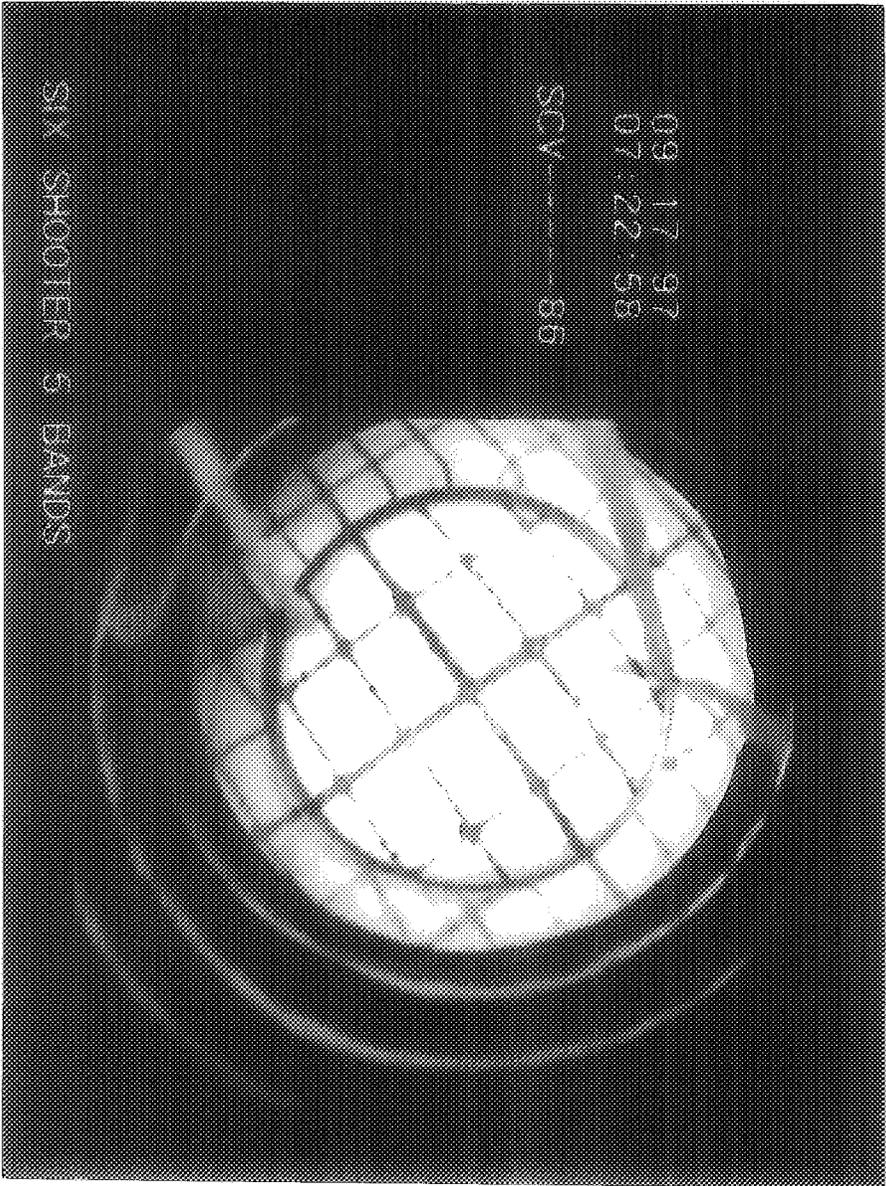
SD

ATTACHMENT VI

PREDICATE SIX SHOT MULTI-BAND LIGATOR



102

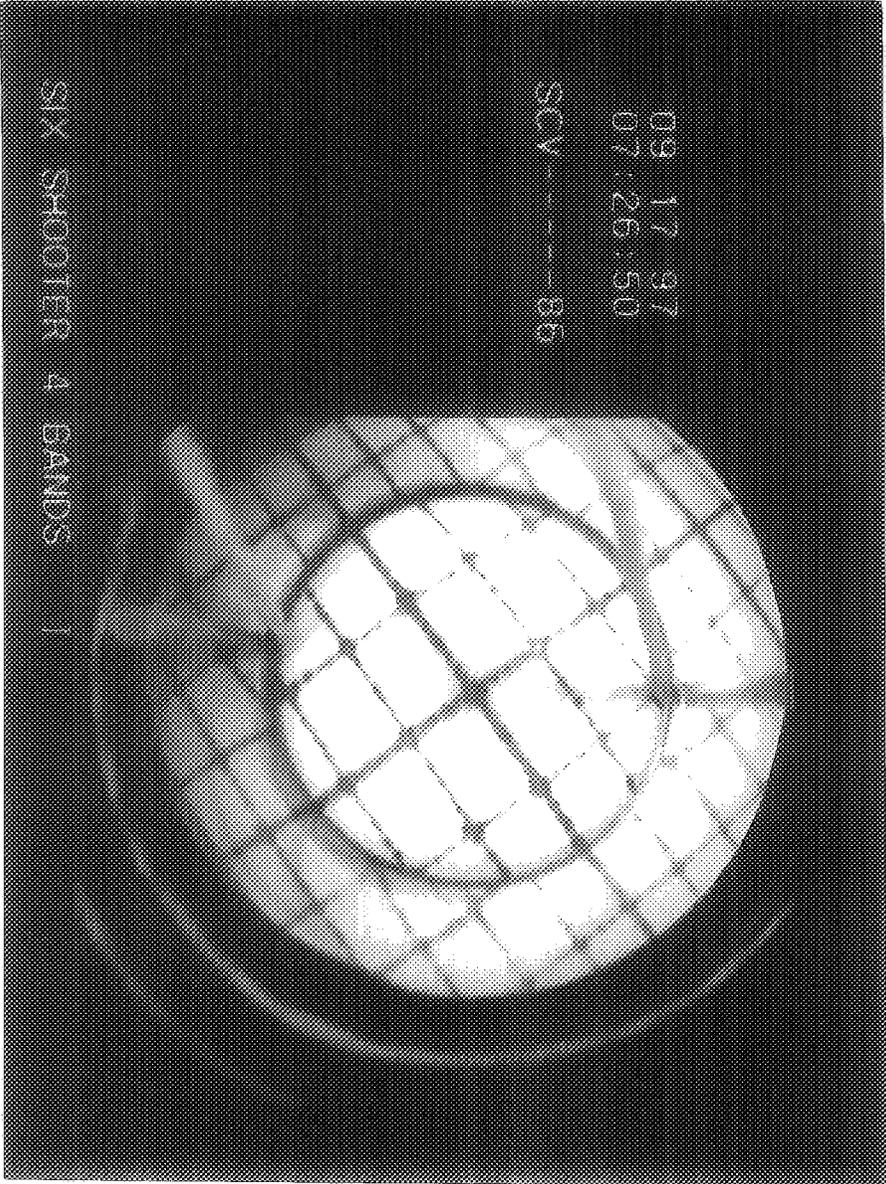


09 17 97
07:22:58

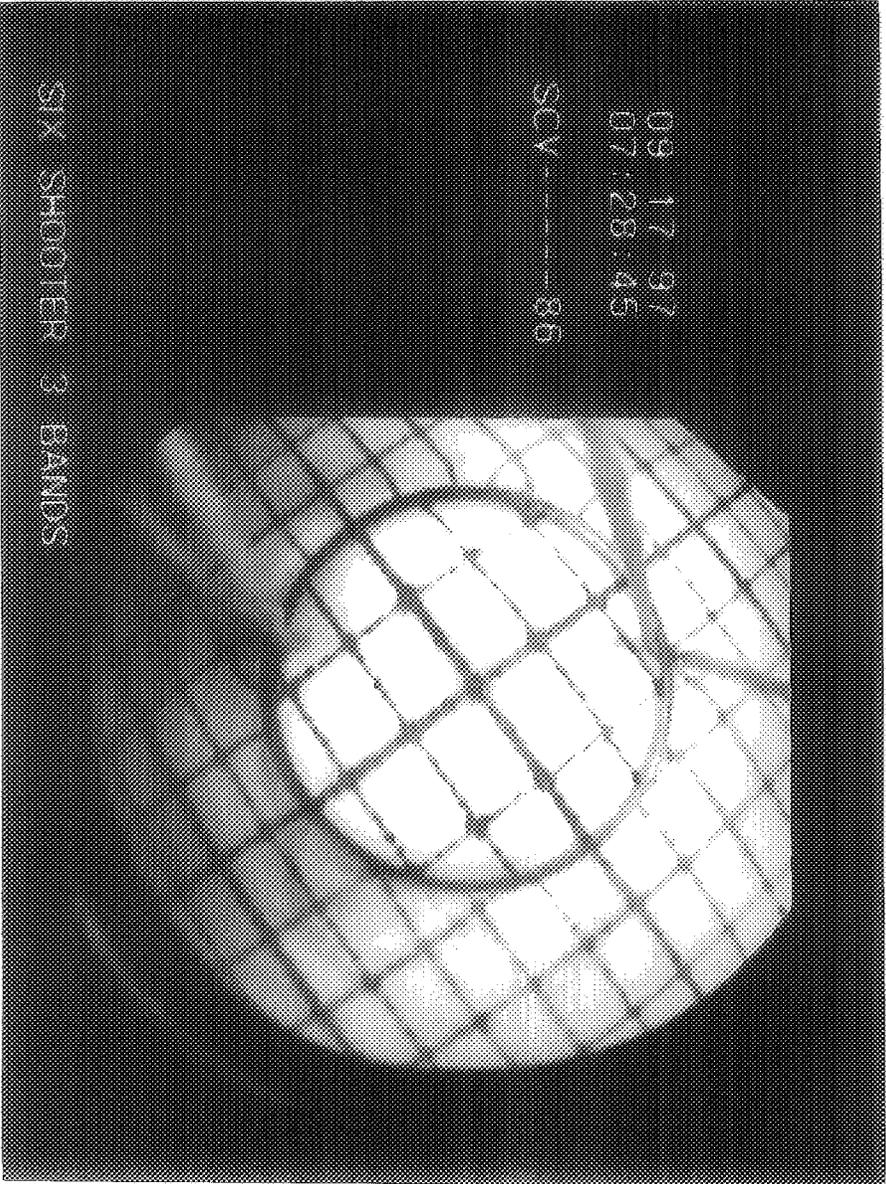
SCV-----86

SIX SHOOTER 5 BANDS

103

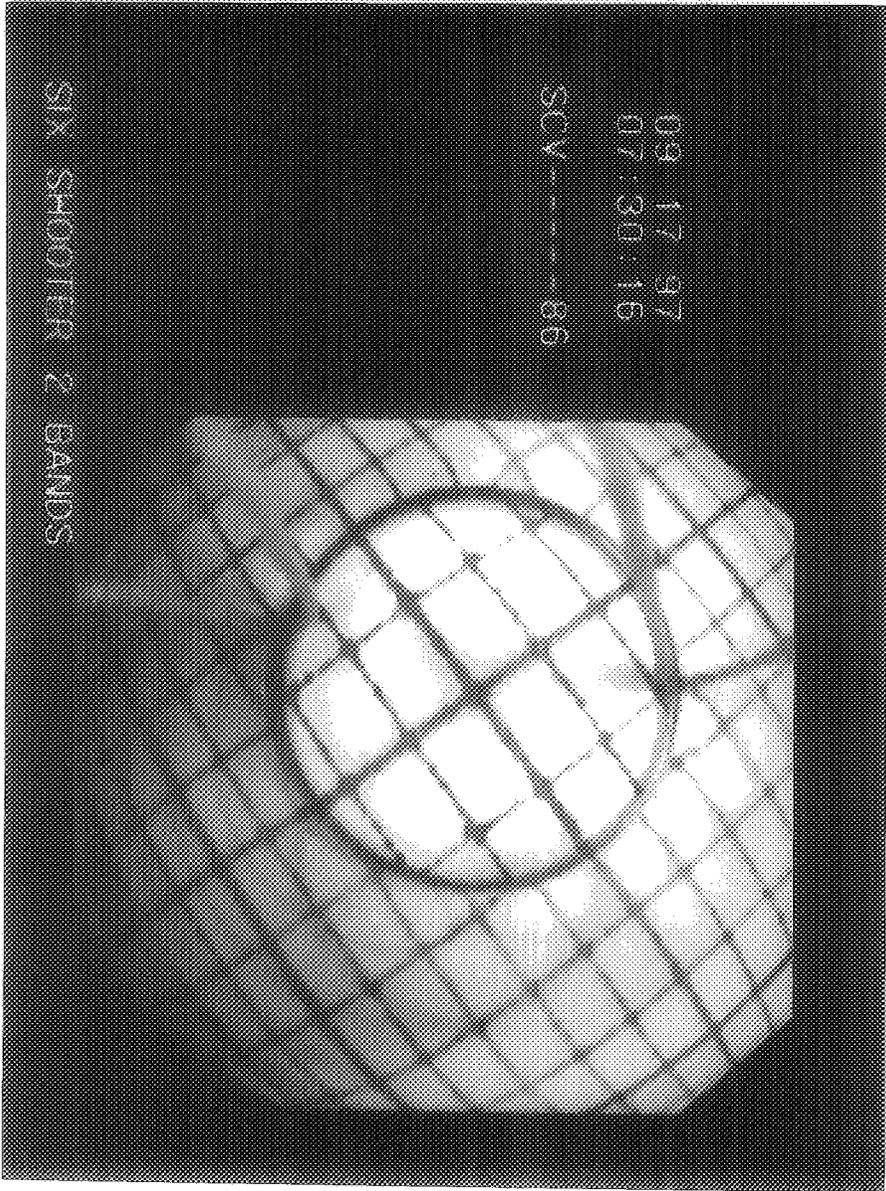


104



SIX SHOOTER 3 BANDS

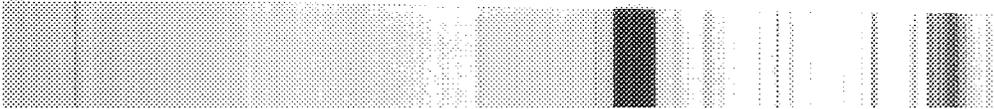
501

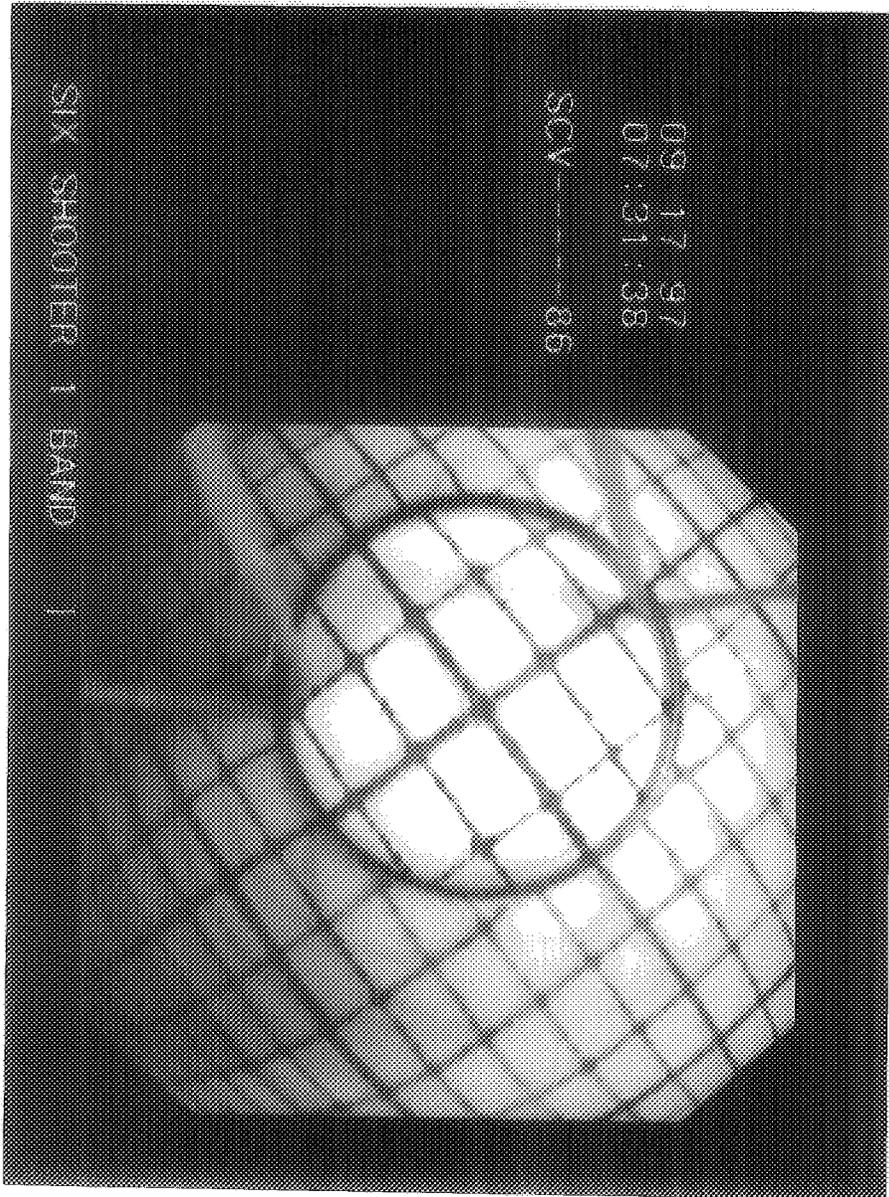


09 17 97
07:30:16
SCV-----86

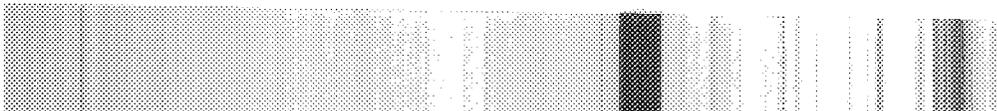
SIX SHOOTER 2 BANDS

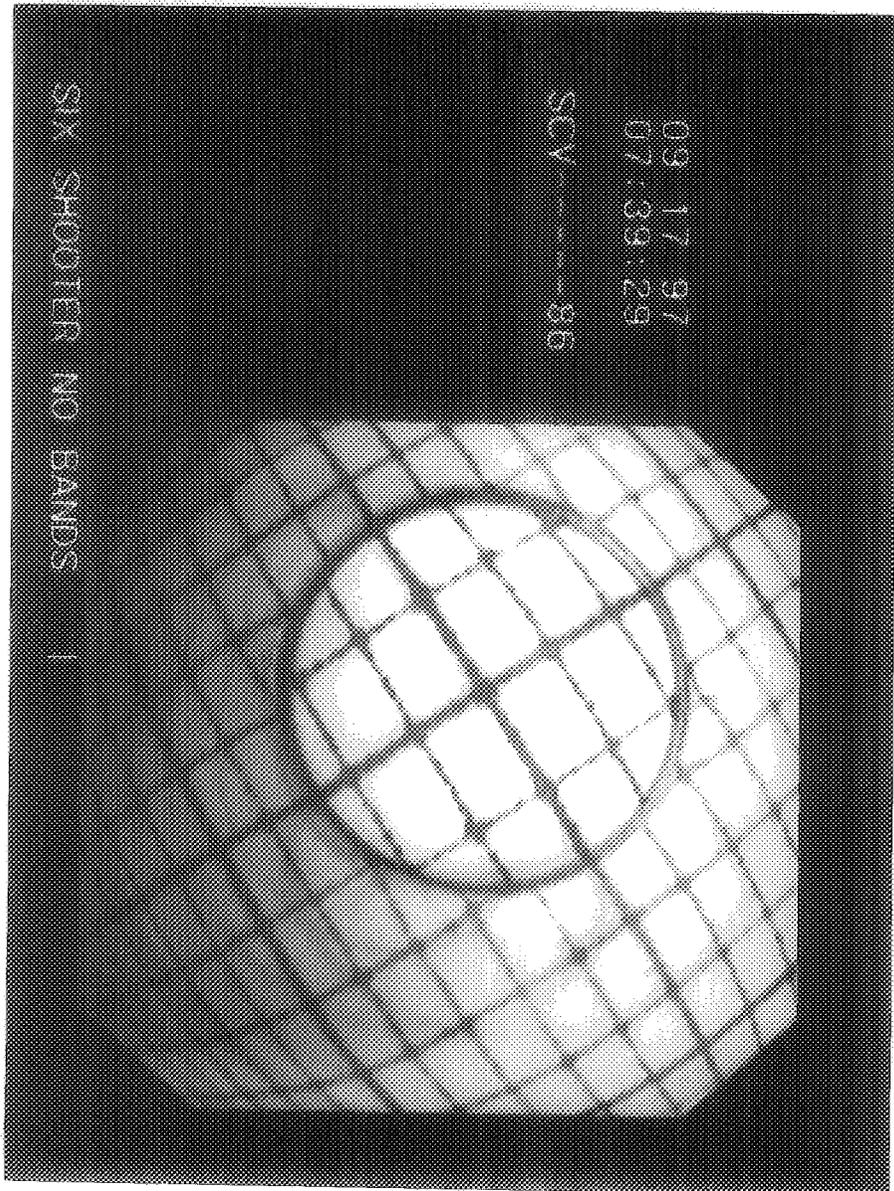
106





107

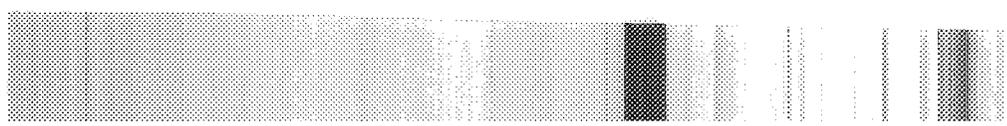




09 17 97
07:39:29
SCV -----86

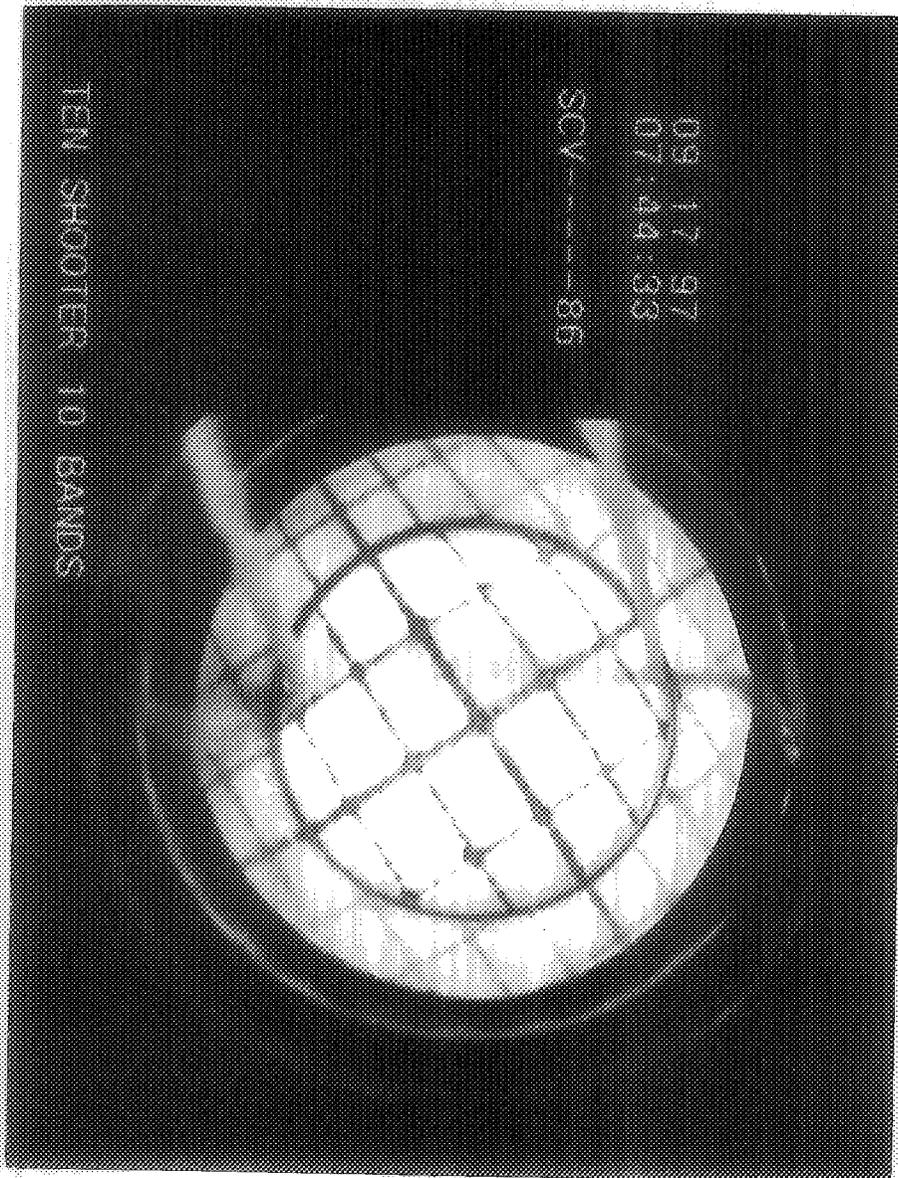
SIX SHOOTER NO BANDS |

801

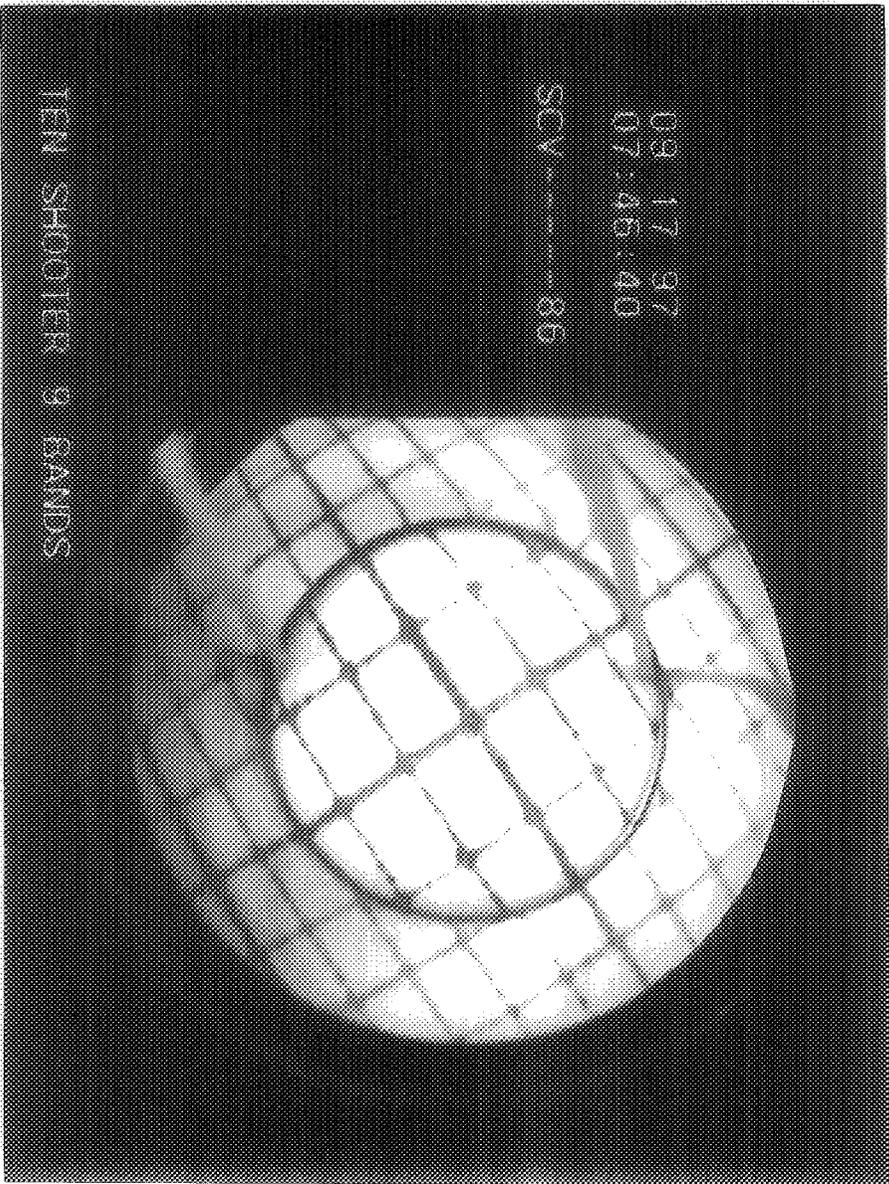


ATTACHMENT VI

TEN SHOT MULTI-BAND LIGATOR

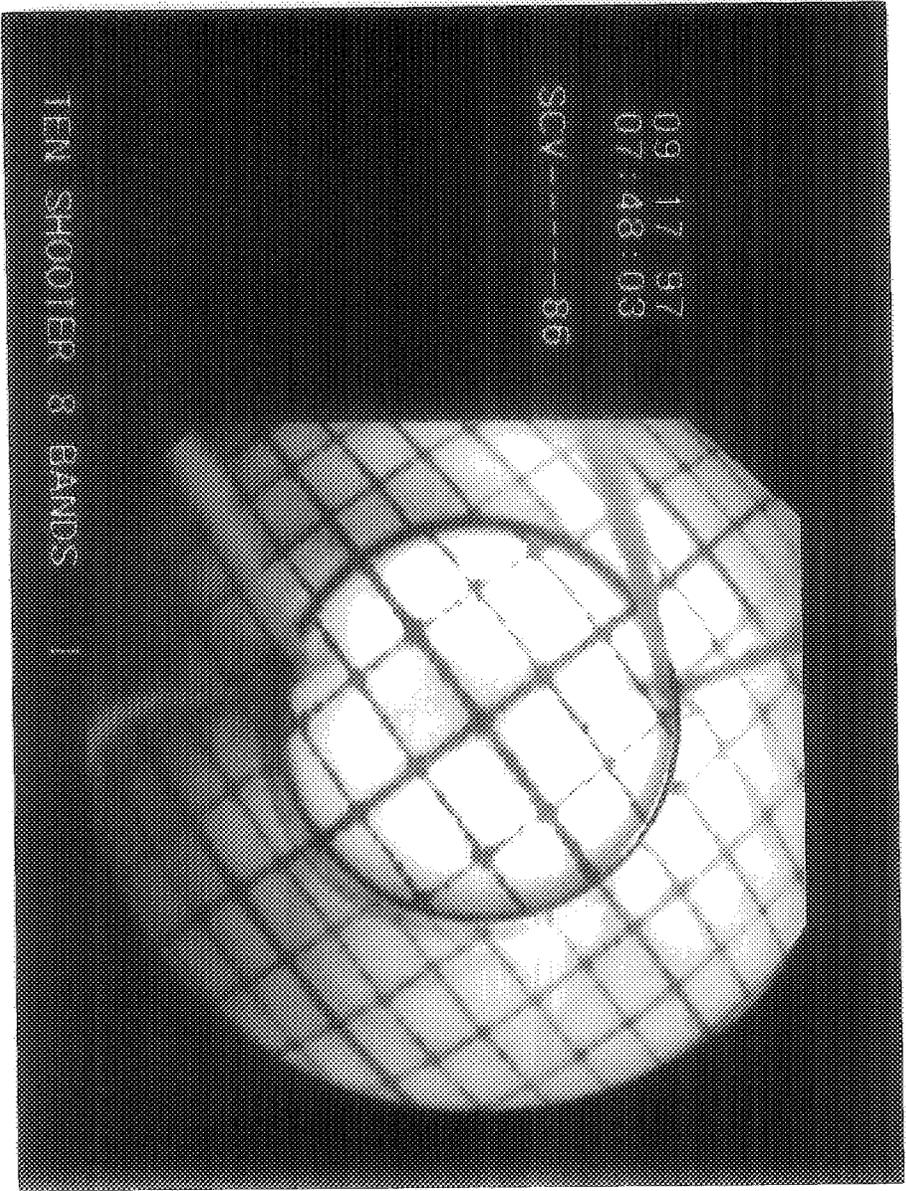


109



110





09 17 97
07:48:03

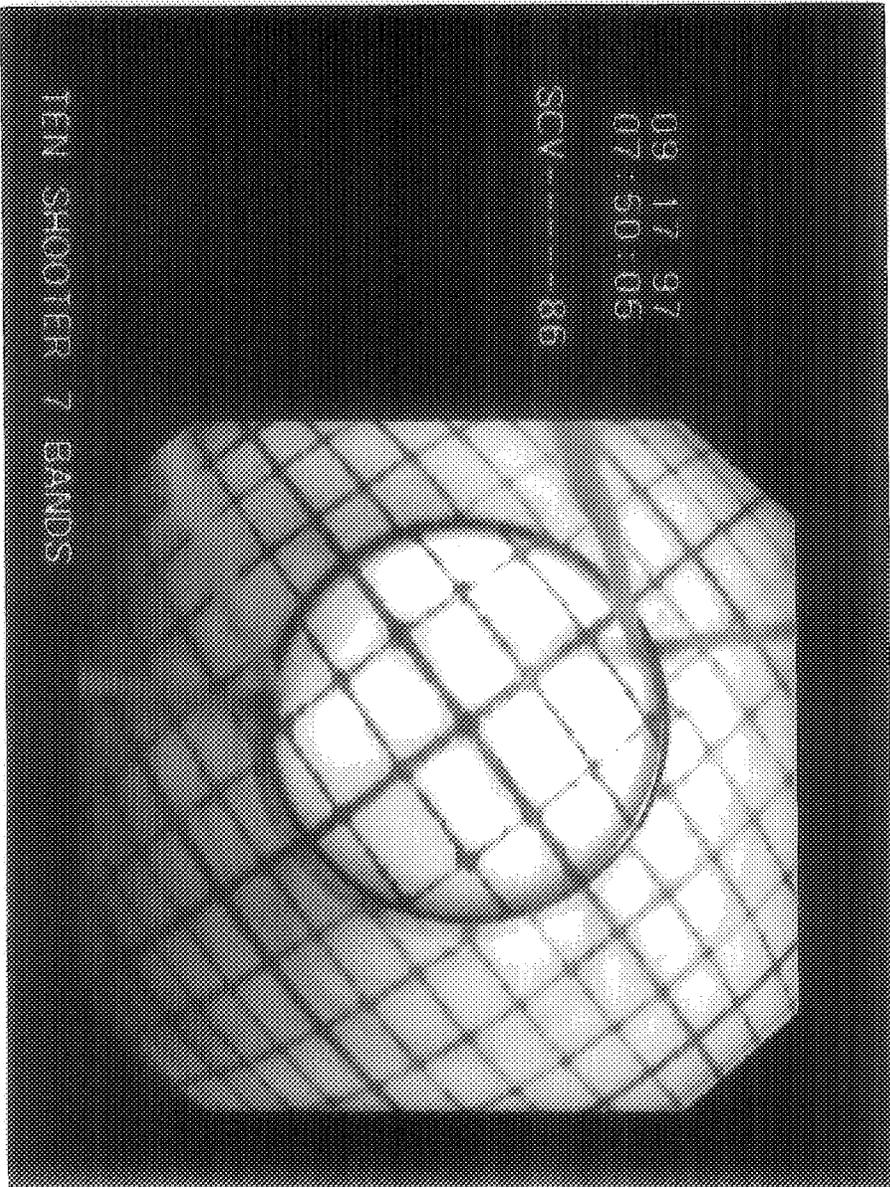
SCV-----86

TEN SHOOTER 8 BANDS |

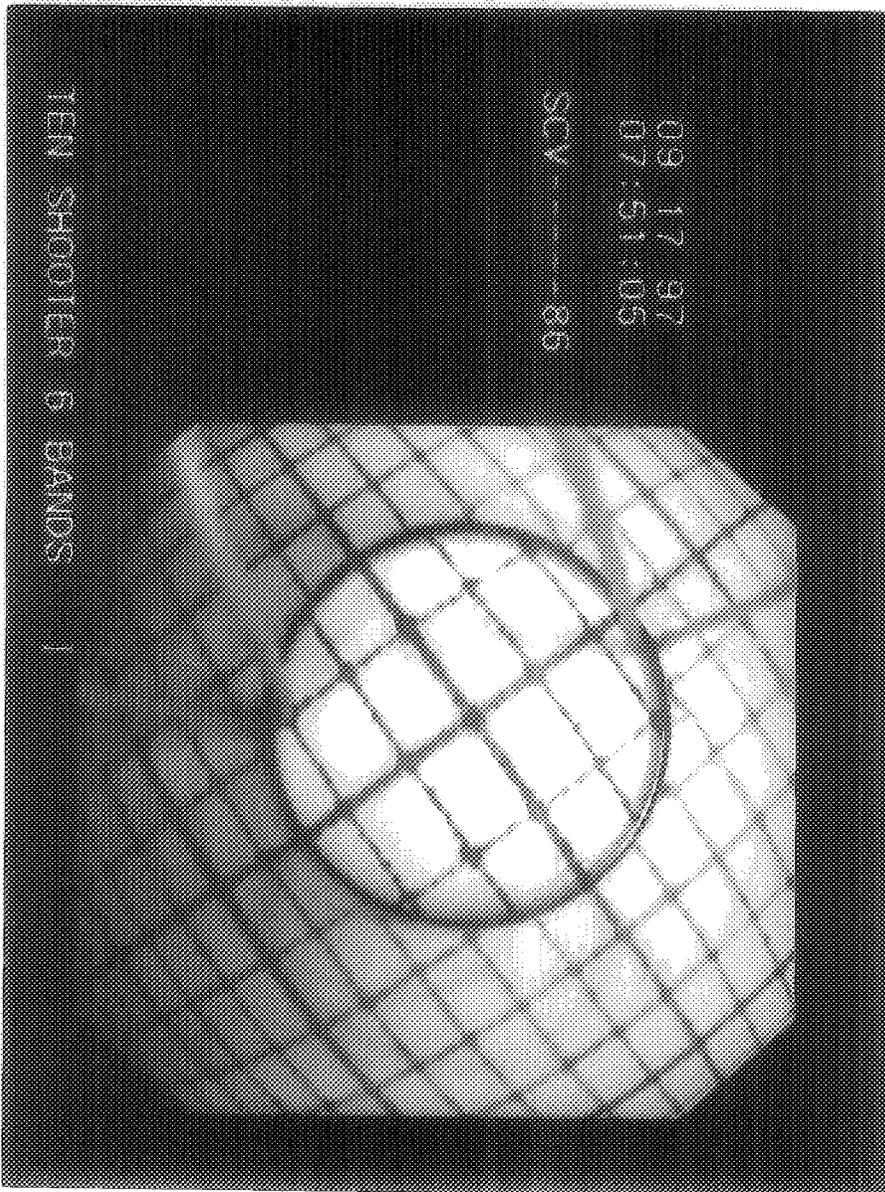
11

11

11



112

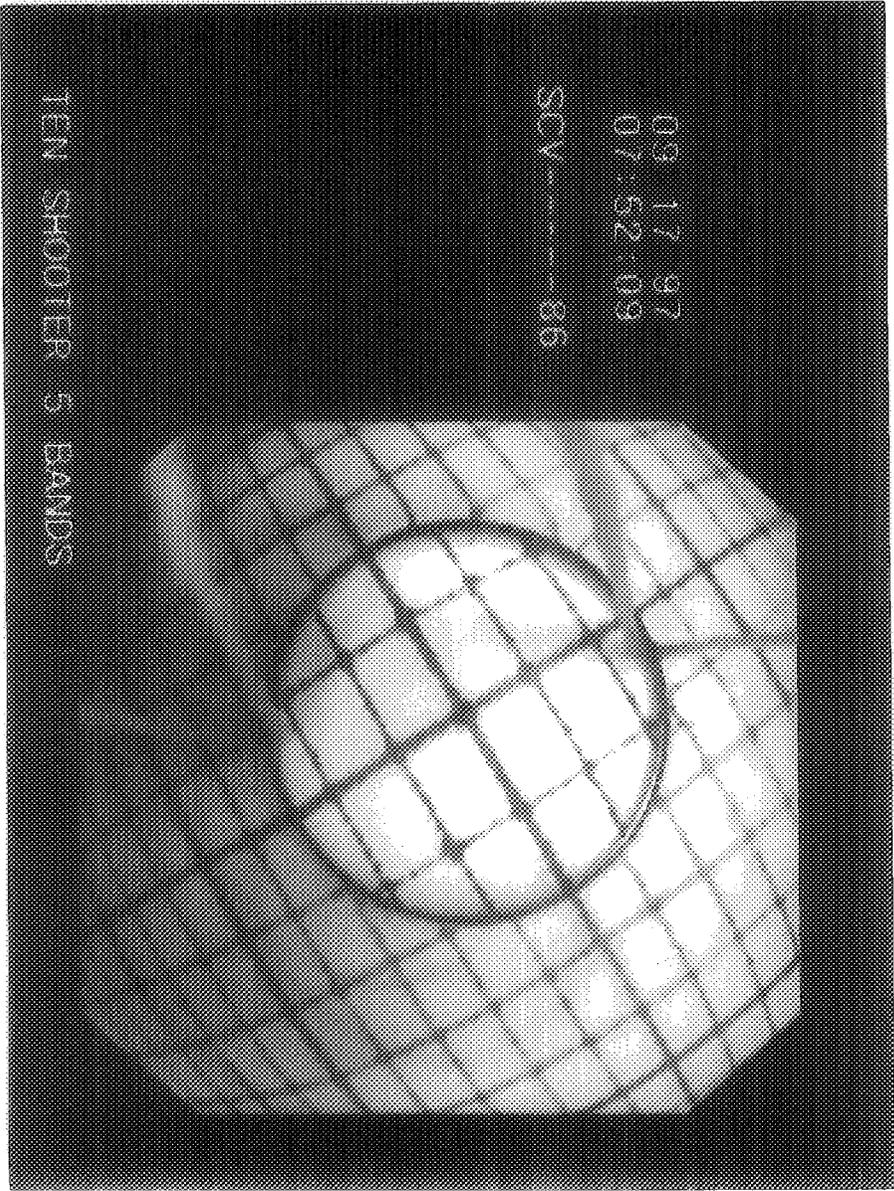


09 17 97
07:51:05

SCV-----86

TEN SHOOTER 6 BANDS

113



11h



09 17 97
07:52:56
SCV-----86

TEN SHOOTER 4 BANDS

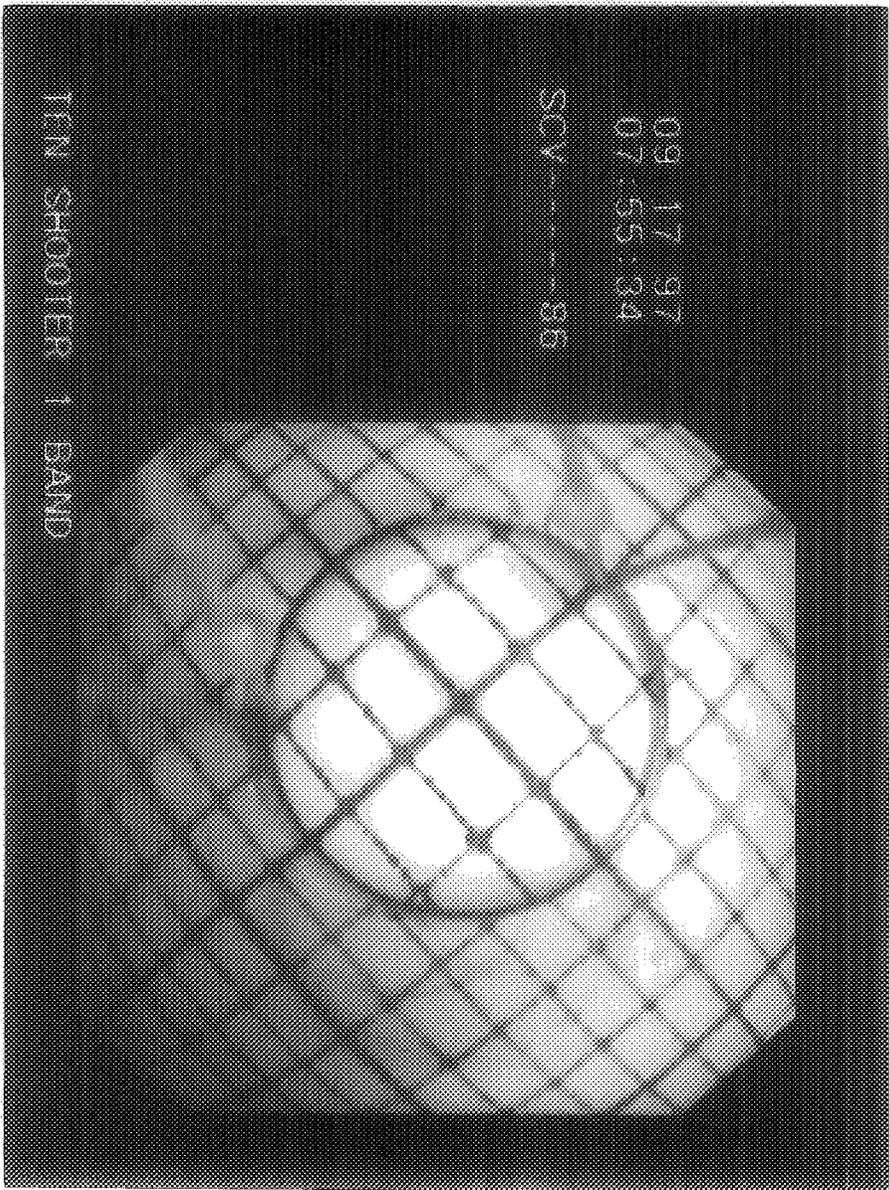
115



09 17 97
07:59:42
SCV-----85

TEN SHOOTER 3 BANDS

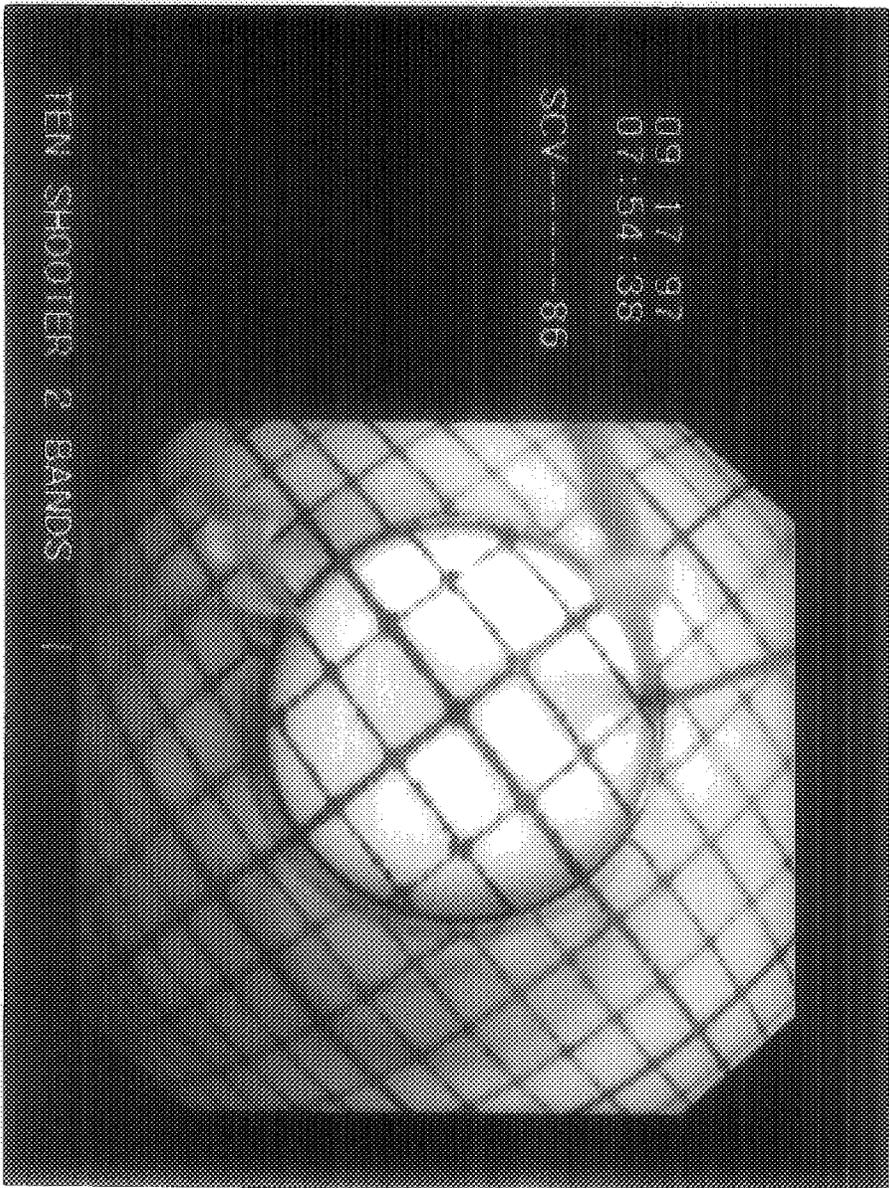
116



5

==

==

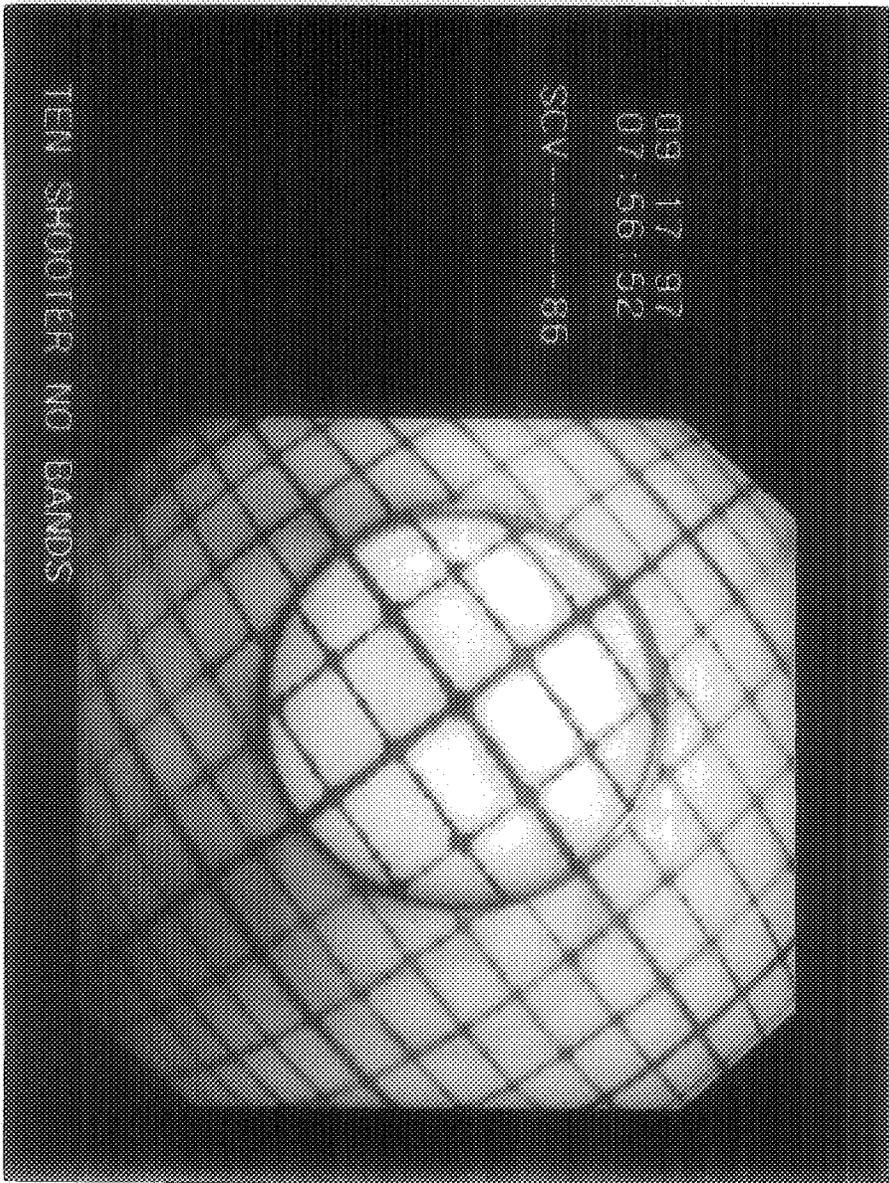


09 17 97
07:54:38

SCV.....86

TEN SHOOTER 2 BANDS

811



09 17 97
07:56:52
SCV.....85

TEN SHOOTER NO BANDS

129