



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Idt)
FOLDER: K840207 - 35 pages
COMPANY: STORZ INSTRUMENT CO. (STORINST)
PRODUCT: CLIP, TANTALUM, OPHTHALMIC (HQW)
SUMMARY: Product: DOUBLE & SINGLE TANTALUM CLIPS

DATE REQUESTED: Oct 8, 2014

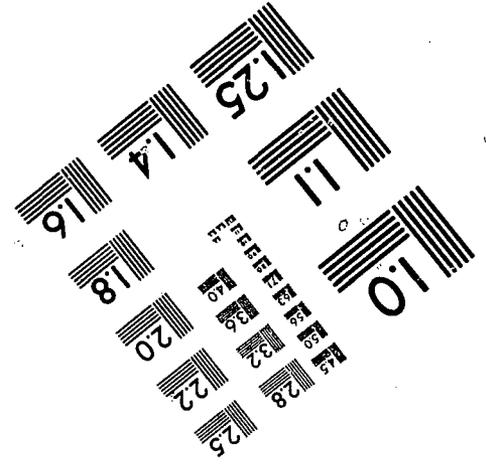
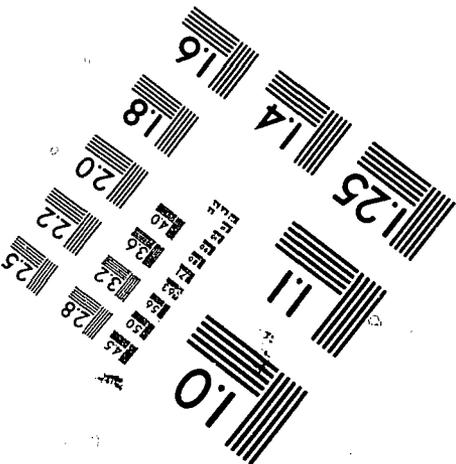
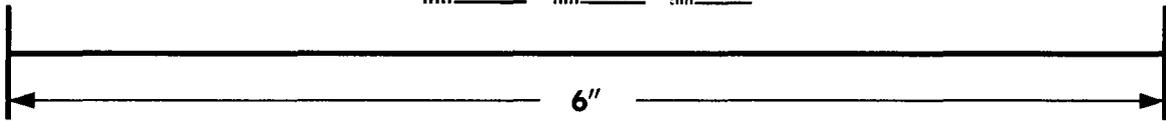
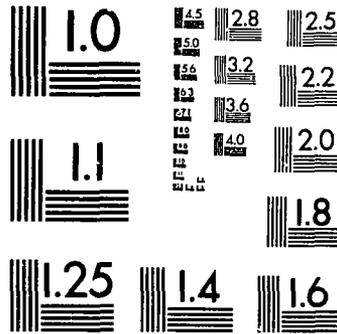
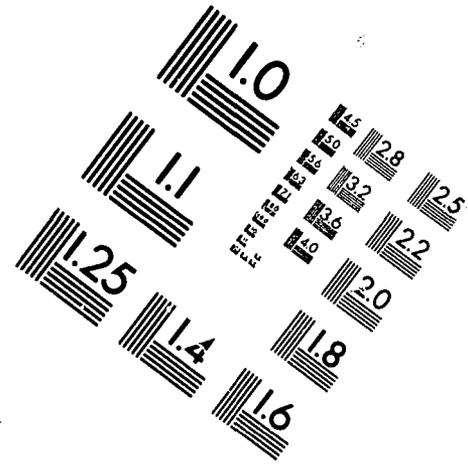
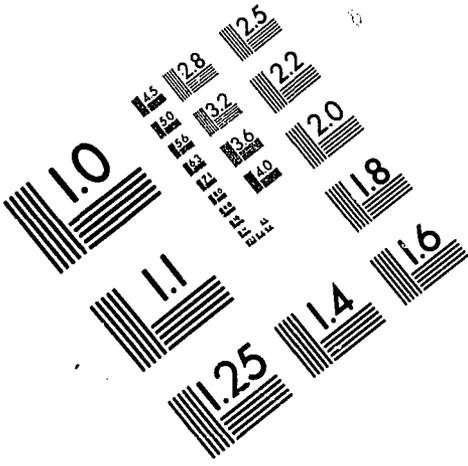
DATE PRINTED: Oct 8, 2014

Note: Printed



KB40207

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K840207



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAR 29 1984

Mr. Stephen M. Doyle
Regulatory/Quality Analyst
Storz Instrument Co.
3365 Tree Court Industrial Blvd.
Saint Louis, Missouri 63122

Re: K840207
Double and Single Tantalum
Clips
Dated: January 11, 1984
Received: January 19, 1984

Dear Mr. Doyle:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be 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 your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

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

FEB. 9 1984

Storz Instrument Company
Attn: Stephen M. Doyle
3365 Tree Ct. Industrial Blvd.
St. Louis, MO. 63122

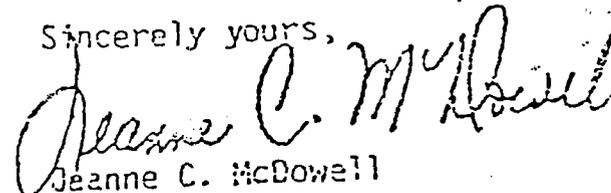
Section : 510K
Number : K840207
Received: 1-19-84
Product : Double and Single tantalum
Clips

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 a unique document control number. Please cite this 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. Questions concerning this submission should be directed to:

Food and Drug Administration
Bureau of Medical Devices
Document Control Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910
(301) 427-7059

Sincerely yours,



Jeanne C. McDowell
Chief
Document Control Center
Bureau of Medical Devices

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Memorandum

3/13/84

Date
From

REVIEWER(S) - NAME(S) John Nagle

Subject

510(k) NOTIFICATION K840207

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

Per my telecon with Mr. Steven Doyle of Storz
 3/13/84, Storz marketed tantalum clips for retinal
 reattachment surgery first in 1973. Storz now wishes
 to use a new supplier. I recommend FDA find the
 new tantalum clips (see page 3 of blue catalog)
 equivalent to ~~clips~~ tantalum clips marketed pre-emptively.

The submitter requests:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Class Code w/Panel:

HQW Class I
Tantalum Clips I
 913-Acting Section Chief

REVIEW:

[Signature] 3/26/84
 (BRANCH CHIEF) (DATE)

FINAL REVIEW:

[Signature] 3/26/84
 (DIVISION DIRECTOR) (DATE)

BEST AVAILABLE COPY

K840207



January 11, 1984

RECEIVED
FBI/AMERICA
1984 JAN 19 AM 10:42
DOCUMENT CONTROL
CENTER

Document Control Center (HFK-20)
NCDRH, OMD
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

Re: 510 (k) Notification

Attn: Document Control Clerk:

This is to notify you of the intention by the Storz Instrument Company to reintroduce the following medical devices to the marketplace:

Classification Name: Clip, Tantalum, Ophthalmic (86 HQW)

Common/Usual Name: Tantalum Clip

Proprietary Names: Double and Single Tantalum Clips

Establishment Registration Number: 1920664

Classification: In the Federal Register of January 26, 1982, the Ophthalmic Device Classification panel recommended that tantalum clips be placed in Class II. To date, no final classification has been published.

Performance Standard: No performance standards for these devices have been established under section 514.

Labeling/Promotional Material: Draft labels and promotional materials are enclosed. The tantalum clips appear on page 3 of the promotional brochure.

Substantial Equivalence: These tantalum clips are similar in function, design, and composition to those manufactured by Medical Instrument Research Associates and formerly distributed by Storz. These clips were on the market prior to May 28, 1976. Attached are copies of the catalogue pages displaying these clips. Please note that this catalogue

Re: 510 (k) Notification

January 11, 1984

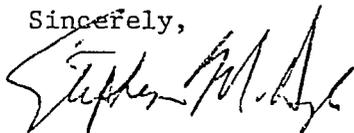
Page 2

was originally copyrighted in 1973. Also, enclosed is a typical material certification for the tantalum used and drawings of the clips themselves.

We consider our intent to market these devices to be confidential commercial information. As such, we request that FDA respect this confidentiality. Our intent to market these devices has been disclosed only to employees of or paid consultants to Storz Instrument Company.

Should any questions arise concerning this notification, please do not hesitate to contact the undersigned at (314) 225-5051, extension 530.

Sincerely,



Stephen M. Doyle
Regulatory/Quality Analyst

SMD/djk
Enclosures

ACTUAL PRODUCT LABELS

ACTUAL SIZE CAT. NO.
E5381-854
DOUBLE TANTALUM CLIP
MANUFACTURED FOR STORZ INSTRUMENT CO., ST. LOUIS, MO.

ACTUAL SIZE CAT. NO.
E5381-853
SINGLE TANTALUM CLIP
MANUFACTURED FOR STORZ INSTRUMENT CO., ST. LOUIS, MO.

ACTUAL SIZE CAT. NO.
E5381-852
(250-STYLE) DOUBLE TANTALUM CLIP
MANUFACTURED FOR STORZ INSTRUMENT CO., ST. LOUIS, MO.

BEST AVAILABLE COPY

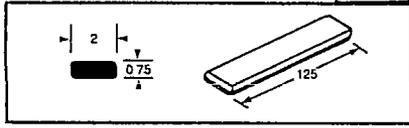
STORZ

Implants for Retinal Detachment Surgery

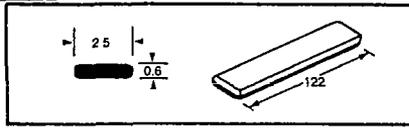
BEST AVAILABLE COPY

CIRCLING BANDS

CIRCLING BANDS



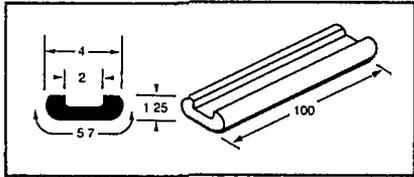
E5381-600 Circling Band (40-Style)



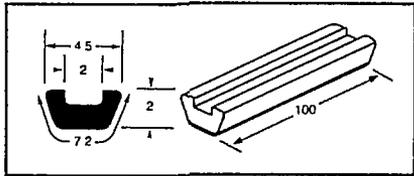
E5381-700 Circling Band (240-Style)

GROOVED IMPLANTS FOR CIRCLING BAND E5381-601

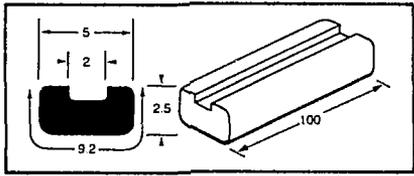
GROOVED IMPLANTS FOR CIRCLING BAND E5381-700 (240-STYLE)



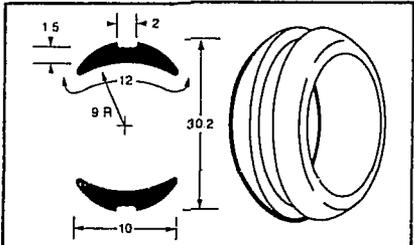
E5381-610 Silicone Strip (20-Style)



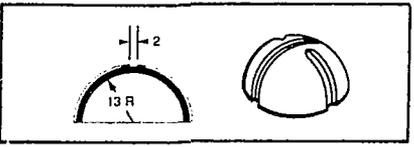
E5381-611 Silicone Strip (31-Style)



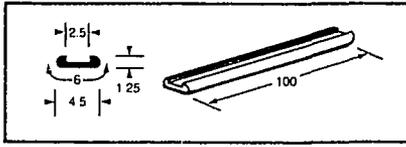
E5381-612 Silicone Strip (32-Style)



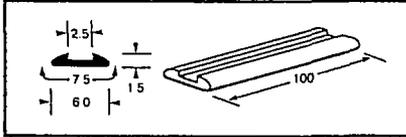
E5381-620 Silicone Tire (78-Style)



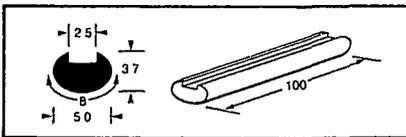
E5381-630 Silicone Hemisphere (77-Style)



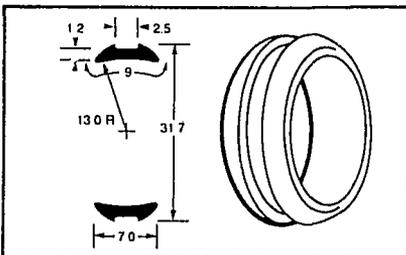
E5381-710 Silicone Strip (219-Style)



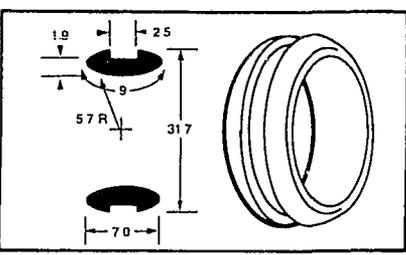
E5381-711 Silicone Strip (220-Style)



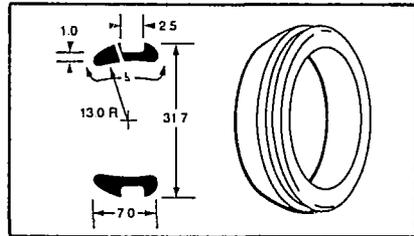
E5381-712 Silicone Strip (225-Style)



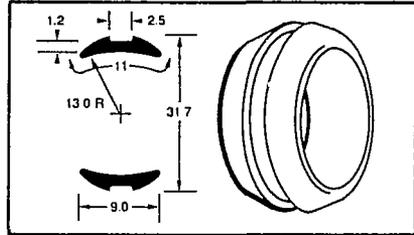
E5381-720 Silicone Tire (277-Style)



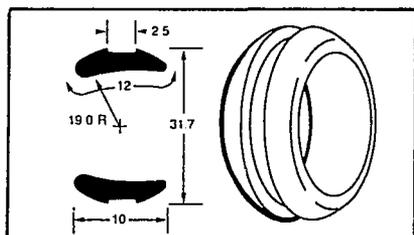
E5381-721 Silicone Tire (287-Style)



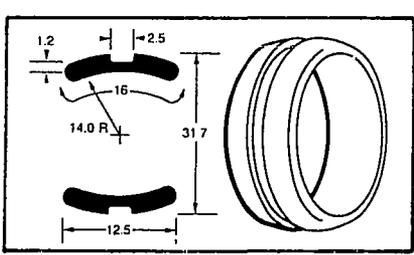
E5381-722 Asymmetrical Tire (276-Style)



E5381-723 Silicone Tire (279-Style)



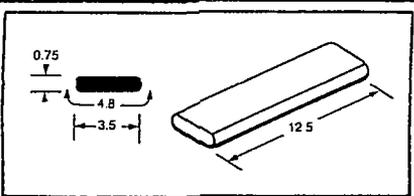
E5381-724 Asymmetrical Tire (280-Style)



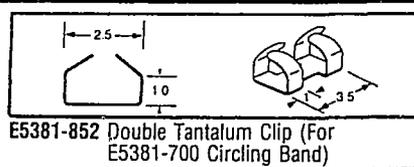
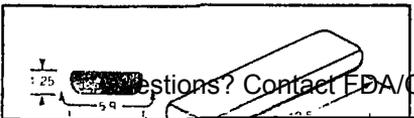
E5381-725 Silicone Tire (281-Style)

IMPLANTS FOR SEGMENTAL BUCKLE

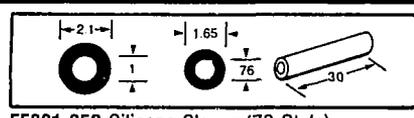
CLIPS AND SLEEVE 1 SECURING CIRCLING B



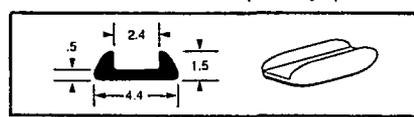
E5381-800 Silicone Strip (41-Style)



E5381-853 Single Tantalum Clip (For E5381-600 Circling Band)



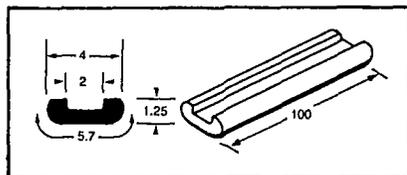
E5381-850 Silicone Sleeve (70-Style)
E5381-851 Silicone Sleeve (270-Style)



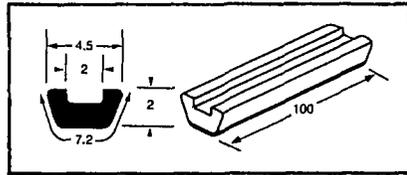
E5381-740 Silicone Boat (260-Style)
(Used with E5381-852 Clip)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIS@FDA.US or 1-800-738-8118

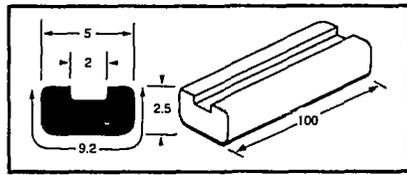
GROOVED IMPLANTS FOR CIRCLING BAND (E5381-600 STYLE)



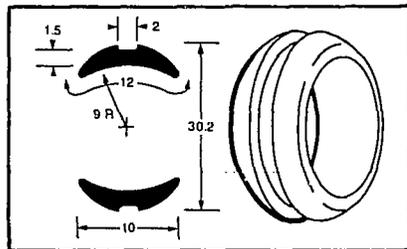
E5381-610 Silicone Strip (20-Style)



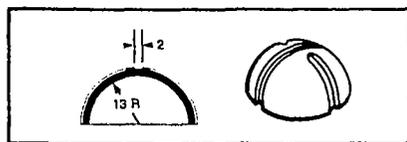
E5381-611 Silicone Strip (31-Style)



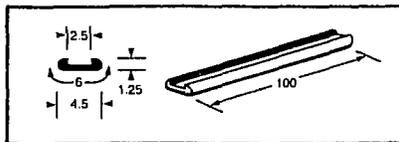
E5381-612 Silicone Strip (32-Style)



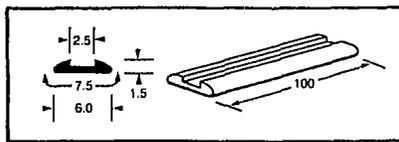
E5381-620 Silicone Tire (78-Style)



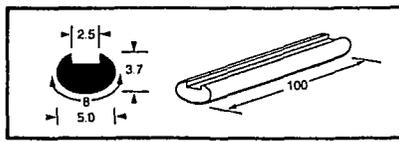
E5381-630 Silicone Hemisphere (77-Style)



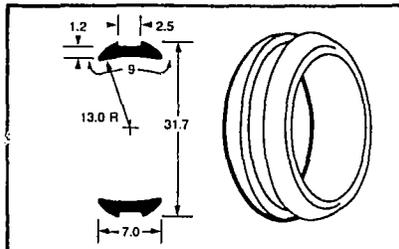
E5381-710 Silicone Strip (219-Style)



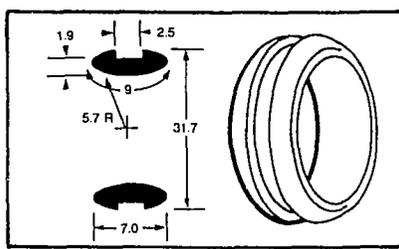
E5381-711 Silicone Strip (220-Style)



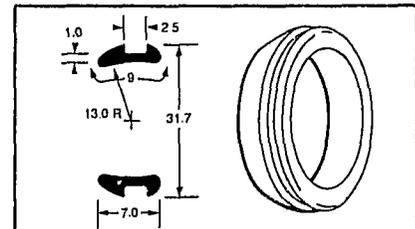
E5381-712 Silicone Strip (225-Style)



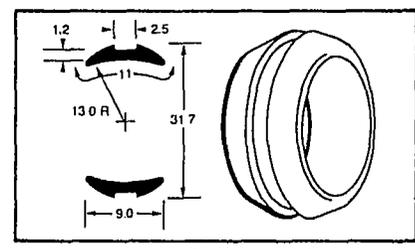
E5381-720 Silicone Tire (277-Style)



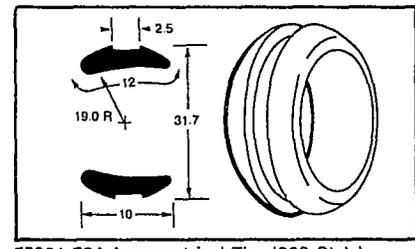
E5381-721 Silicone Tire (287-Style)



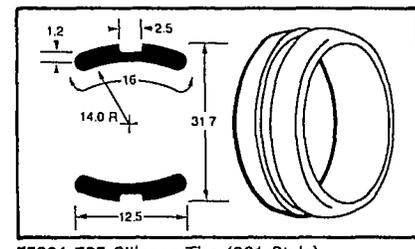
E5381-722 Asymmetrical Tire (276-Style)



E5381-723 Silicone Tire (279-Style)

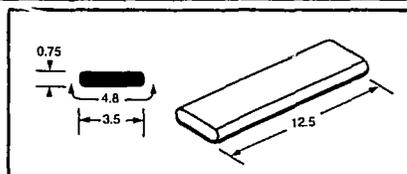


E5381-724 Asymmetrical Tire (280-Style)

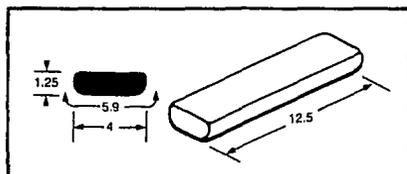


E5381-725 Silicone Tire (281-Style)

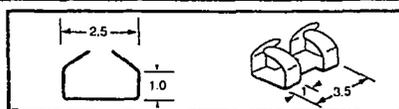
IMPLANTS FOR SEGMENTAL BUCKLE



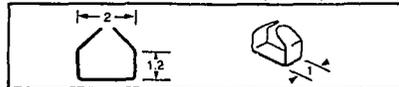
E5381-800 Silicone Strip (41-Style)



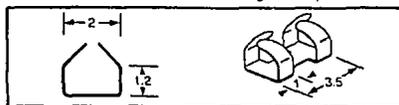
E5381-801 Silicone Strip (42-Style)



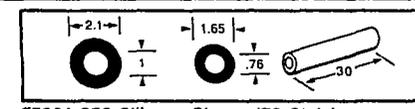
E5381-852 Double Tantalum Clip (For E5381-700 Circling Band)



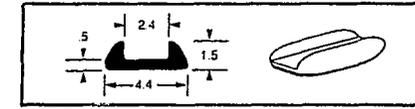
E5381-853 Single Tantalum Clip (For E5381-600 Circling Band)



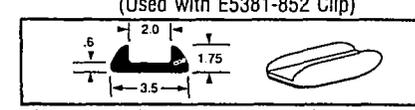
E5381-854 Double Tantalum Clip (For E5381-600 Circling Band)



E5381-850 Silicone Sleeve (70-Style)
 E5381-851 Silicone Sleeve (270-Style)

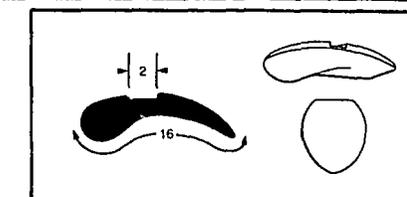


E5381-740 Silicone Boat (260-Style)
 (Used with E5381-852 Clip)

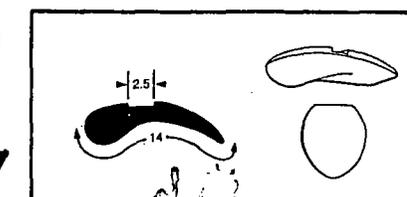


E5381-640 Silicone Boat (60-Style)
 (Used with E5381-853 Clip)

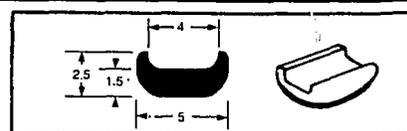
ADDING BUCKLING



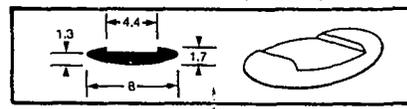
E5381-650 Wedge (135-Style)



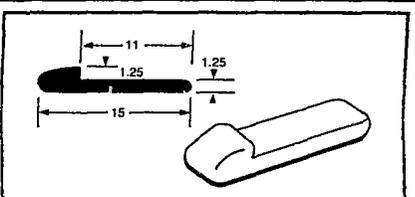
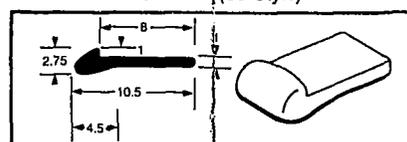
E5381-750 Wedge (139-Style)



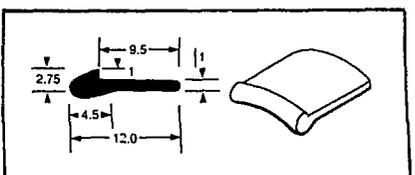
E5381-860 Silicone Button (22-Style)



E5381-861 Silicone Pad (80-Style)



E5381-871 Meridional Implant (103-Style)



E5381-872 Curved Meridional Implant

GROOVED IMPLANTS FOR CIRCLING BAND E5381-700 (240-STYLE)

CLIPS AND SLEEVE FOR SECURING CIRCLING BANDS

IMPLANTS THAT PROVIDE ADDITIONAL BUCKLING



Implants for Retinal Detachment Surgery

Storz® offers a complete line of implants to perform the scleral buckling procedure for retinal reattachment surgery.

DESCRIPTION:

Each implant is made of soft elastic medical grade silicone that has been tested to be nontoxic. Dimensional descriptions of each implant are found on the reverse side of this page.

METHOD OF USE AND INDICATIONS:

Circling Bands E5381-600 (40-Style) and E5381-700 (240-Style)

Storz provides two circling bands: E5381-600 (40-Style) and E5381-700 (240-Style). Both bands have the proper tensile strength for maintaining the implant in the proper position while exerting correct pressure to form a permanent buckle. Scleral erosion is minimized.

Clips, Sleeves and Silicone Boats Used to Secure Circling Bands

Storz offers 3 tantalum clips and two silicone sleeves to secure the encircling bands.

Double tantalum clip (E5381-852) is used to secure the E5381-700 circling band (240-Style). Single tantalum clip (E5381-853) and double tantalum clip (E5381-854) are used to secure the E5381-600 circling band (40-Style). A two step procedure can be used to close the double tantalum clips around the overlapped ends of the circling band. The surgeon can partially close the clip to place the initial tension on the circling band. The band can then be adjusted to optimal tension after which the clip can be completely closed.

Silicone boats E5381-740 (260-Style) and E5381-640 (60-Style) rest under the tantalum clips and act as a pad to help avoid the possibility of erosion.

Implants For the E5381-600 Circling Band (40-Style)

Storz has developed 3 silicone strips, a silicone tire and a silicone hemisphere to be used in conjunction with the E5381-600 circling band. These grooved implants fit under the circling band.

The three silicone strips, E5381-610 (20-Style), E5381-611 (31-Style) and E5381-612 (32-Style) are used for a narrow scleral bed of any length.

The silicone tire, E5381-620 (78-Style), is used for a wide scleral bed.

The Silicone Hemisphere E5381-630 (77-Style) is used to correct multiple or huge breaks which cover a large area of the retina.

Implants For the E5381-700 Circling Band (240-Style)

Storz has developed three silicone strips and six silicone tires to be used in conjunction with the E5381-700 circling band (240-Style). These grooved implants fit under the circling band.

Two silicone strips, E5381-710 (219-Style) and E5381-711 (220-Style), are used for narrow scleral beds. The E5381-712 (225-Style) silicone strip is indicated when a high buckle is required.

The E5381-722 (276-Style), E5381-720 (277-Style), E5381-723 (279-Style), E5381-724 (280-Style) and E5381-725 (281-Style) silicone tires are indicated for wide scleral beds. They have a concave inner surface. Tire E5381-722 is assymmetrical and useful for breaks located near the ora serrata.

Tire E5381-725 is designed to correct multiple breaks or huge breaks which cover a large area of the retina. The convex inner surface of the E5381-721 (287-Style) provides a high scleral buckle.

Implants for Segmental Buckle

E5381-800 (41-Style) and E5381-801 (42-Style) are straight ungrooved implants. They can be used as permanent implants when trap door procedures are indicated.

Implants That Provide Additional Scleral Buckling

Storz has developed six implants which provide additional scleral buckling.

The E5381-860 silicone button (22-Style) is used under the E5381-710, E5381-610 and E5381-611 implants to create a higher buckle.

To provide additional buckling in the meridional direction, Storz has developed three implants: E5381-870 (106-Style), E5381-871 (103-Style), and E5381-872 (112-Style). These implants are used in conjunction with the curved or grooved implants.

The silicone wedges are used with grooved radial implants to affect maximum buckling. The E5381-650 wedge is used with the E5381-600 circling band while the E5381-750 wedge is used with the E5381-700 circling band. Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

METHOD OF USE AND INDICATIONS:

Circling Bands E5381-600 (40-Style) and E5381-700 (240-Style)

Storz provides two circling bands: E5381-600 (40-Style) and E5381-700 (240-Style). Both bands have the proper tensile strength for maintaining the implant in the proper position while exerting correct pressure to form a permanent buckle. Scleral erosion is minimized.

Clips, Sleeves and Silicone Boats Used to Secure Circling Bands

Storz offers 3 tantalum clips and two silicone sleeves to secure the encircling bands.

Double tantalum clip (E5381-852) is used to secure the E5381-700 circling band (240-Style). Single tantalum clip (E5381-853) and double tantalum clip (E5381-854) are used to secure the E5381-600 circling band (40-Style). A two step procedure can be used to close the double tantalum clips around the overlapped ends of the circling band. The surgeon can partially close the clip to place the initial tension on the circling band. The band can then be adjusted to optimal tension after which the clip can be completely closed.

Silicone boats E5381-740 (260-Style) and E5381-640 (60-Style) rest under the tantalum clips and act as a pad to help avoid the possibility of erosion.

Implants For the E5381-600 Circling Band (40-Style)

Storz has developed 3 silicone strips, a silicone tire and a silicone hemisphere to be used in conjunction with the E5381-600 circling band. These grooved implants fit under the circling band.

The three silicone strips, E5381-610 (20-Style), E5381-611 (31-Style) and E5381-612 (32-Style) are used for a narrow scleral bed of any length.

The silicone tire, E5381-620 (78-Style), is used for a wide scleral bed.

The Silicone Hemisphere E5381-630 (77-Style) is used to correct multiple or huge breaks which cover a large area of the retina.

Implants For the E5381-700 Circling Band (240-Style)

Storz has developed three silicone strips and six silicone tires to be used in conjunction with the E5381-700 circling band (240-Style). These grooved implants fit under the circling band.

Two silicone strips, E5381-710 (219-Style) and E5381-711 (220-Style), are used for narrow scleral beds. The E5381-712 (225-Style) silicone strip is indicated when a high buckle is required.

The E5381-722 (276-Style), E5381-720 (277-Style), E5381-723 (279-Style), E5381-724 (280-Style) and E5381-725 (281-Style) silicone tires are indicated for wide scleral beds. They have a concave inner surface. Tire E5381-722 is assymmetrical and useful for breaks located near the ora serrata.

Tire E5381-725 is designed to correct multiple breaks or huge breaks which cover a large area of the retina. The convex inner surface of the E5381-721 (287-Style) provides a high scleral buckle.

Implants for Segmental Buckle

E5381-800 (41-Style) and E5381-801 (42-Style) are straight ungrooved implants. They can be used as permanent implants when trap door procedures are indicated.

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To provide additional buckling in the meridional direction, Storz has developed three implants: E5381-870 (106-Style), E5381-871 (103-Style), and E5381-872 (112-Style). These implants are used in conjunction with the curved or grooved implants.

The silicone wedges are used with grooved radial implants to affect maximum buckling. The E5381-650 wedge is used with the E5381-600 circling band while the E5381-750 wedge is used with the E5381-700 circling band.

The silicone pad, E5381-861 (80-Style) is used to close scleral ruptures.

PACKAGING:

Storz silicone and tantalum implants are packaged sterile, five implants per box. Each implant is stored in a flip top plastic container which is wrapped in a Tyvek® pouch. The dispenser box permits easy removal and storage. The entire contents of each box are sterilized.

STERILIZATION:

Implants have been packaged sterile using ETO gas sterilization.

WARNING:

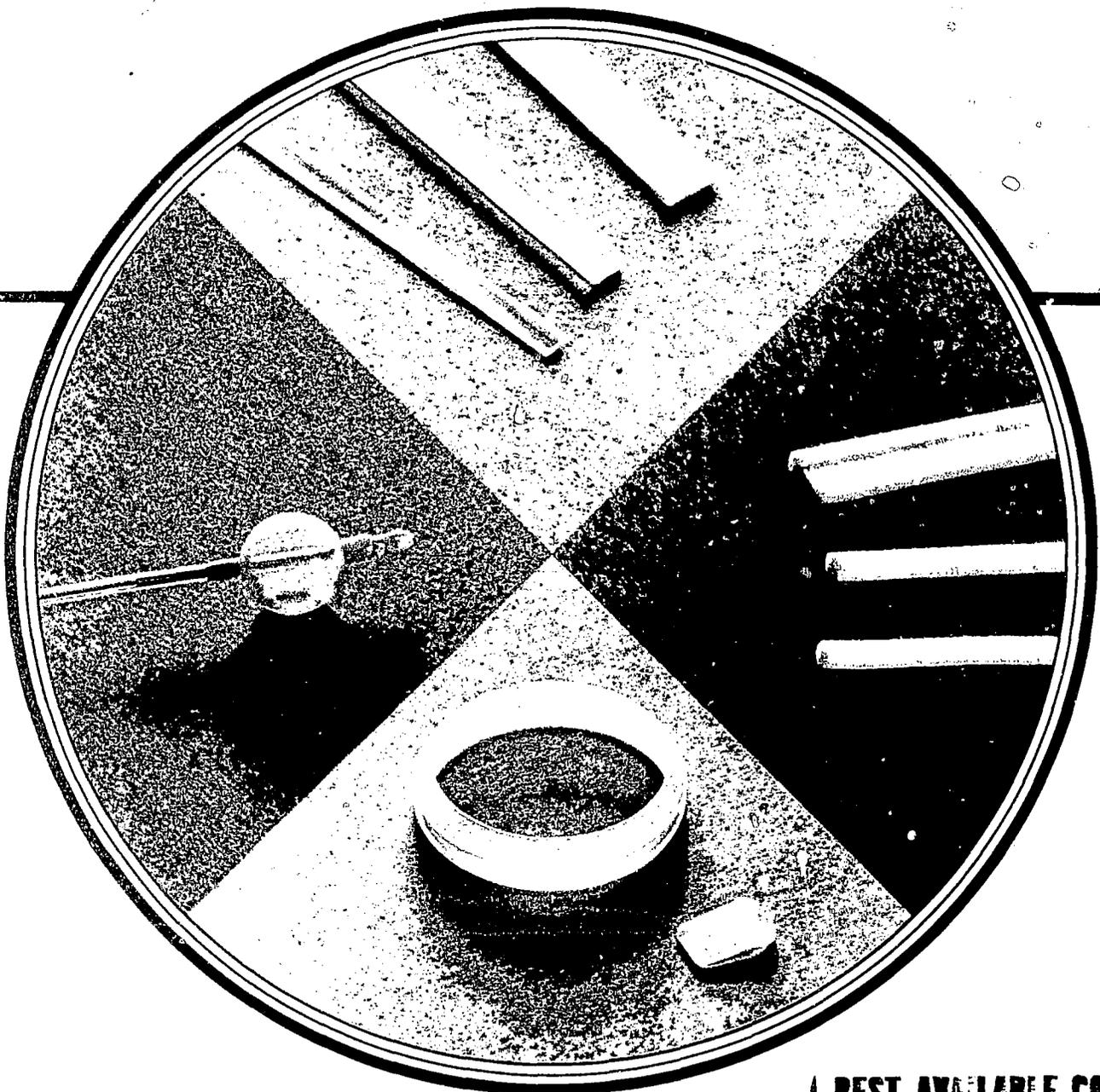
Federal (USA) Law restricts this device to sale by or on the order of a physician. Sterility not guaranteed if the package has been opened or damaged.

Tyvek is a registered trademark of E. L. DuPont



storz[®]

Implants for Retinal Detachment Surgery



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Storz®, the industry leader in providing the finest quality ophthalmic instruments and surgical specialties, now offers a complete line of implants for retinal detachment corrective procedures.

- Silicone Retinal Implants, Circling Bands, and Segmental Buckles
- Scleral Buckling Balloon Catheters (Lincoff Design)
- Scleral Sponge II (Lincoff Design)

Storz has developed a complete assortment of traditional implants, circling bands and segmental buckles for performing scleral buckling procedures. The Storz retinal implants are manufactured of the finest non toxic soft medical grade silicone. The implants can be easily shaped and molded as desired by the surgeon.

The scleral buckling balloon catheter is a new implant designed by Dr. Harvey Lincoff and distributed by Storz exclusively. The implant reduces surgical complications, provides more rapid visual acuity recovery, helps avoid scleral erosion problems and reduces infection or diplopia.

For procedures requiring a soft, closed cell, silicone elastomer sponge Storz offers Scleral Sponge II. Developed by Dr. Lincoff in conjunction with Dow-Corning®, Scleral Sponge II is available in cylindrical, oval and grooved designs in a variety of sizes.

Storz is excited about its ophthalmic implant product line. This brochure provides catalogue numbers and detailed descriptions for each implant.

Further inquiries concerning Storz Implants for Retinal Detachment Surgery can be made through your Storz sales representative or by calling Storz National Customer Service 800-325-9500.

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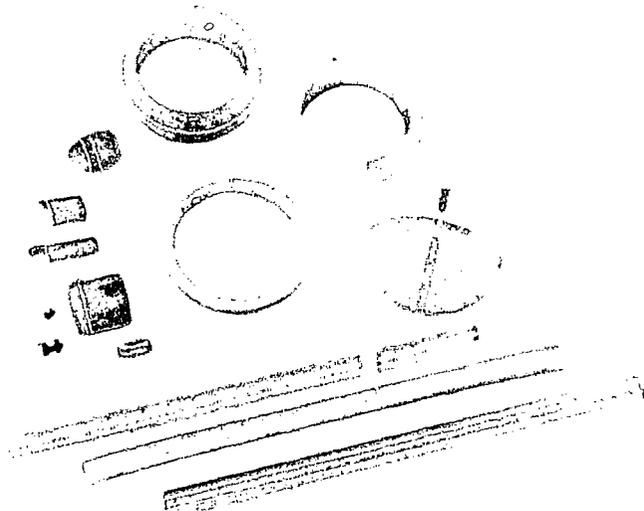
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IMPLANTS FOR SCLERAL BUCKLING

Storz® offers a complete line of implants to perform the scleral buckling procedure. Each implant, whether for the encircling or segmental buckle is:

- Made of soft, elastic medical grade silicone
- Nontoxic, nonantigenic
- Easy to mold
- Packaged sterile, five implants per dispenser box. Each implant is stored in a flip top plastic container which is wrapped in a Tyvek® pouch.

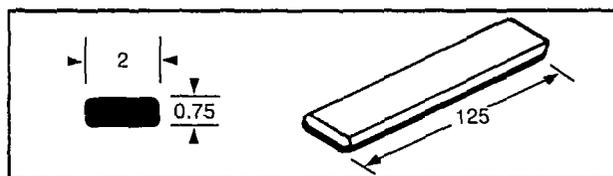


CIRCLING BANDS

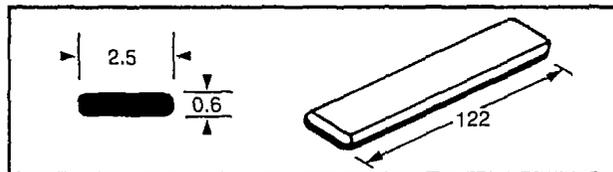
There are two circling bands available: E5381-600 and E5381-700.

E5381-600
Circling Band (40-Style)
2.0mm wide.

E5381-700
Circling Band (240-Style)
2.5mm wide.



E5381-600



E5381-700

CLIPS AND SLEEVE FOR SECURING CIRCLING BANDS

Storz offers three tantalum clips and two silicone sleeves to secure overlapped ends of the circling bands.

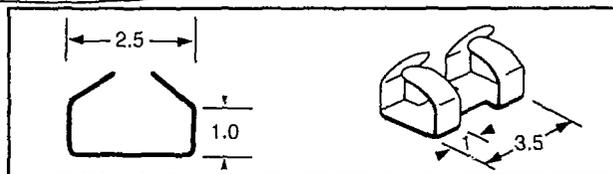
E5381-852
Double Tantalum Clip (250-Style)
For E5381-700 Circling Band (240-Style).

E5381-854
Double Tantalum Clip
For E5381-600 Circling Band (40-Style).

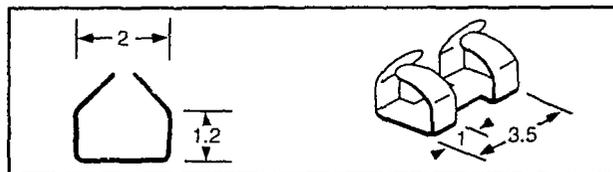
E5381-853
Single Tantalum Clip
For E5381-600 Circling Band (40-Style).

E5381-850
Silicone Sleeve (70-Style).

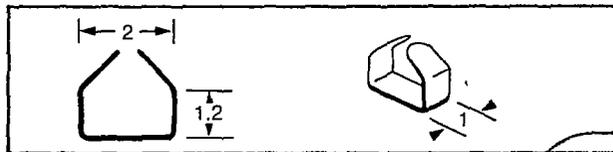
E5381-851
Silicone Sleeve (270-Style).



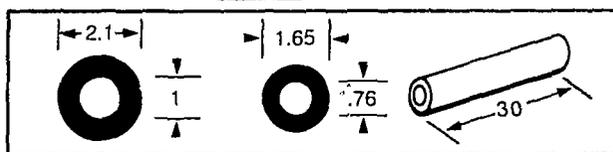
E5381-852



E5381-854



E5381-853



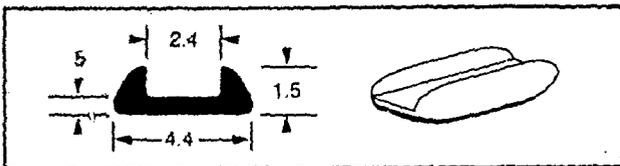
E5381-850

E5381-851

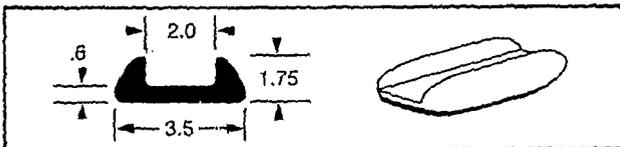
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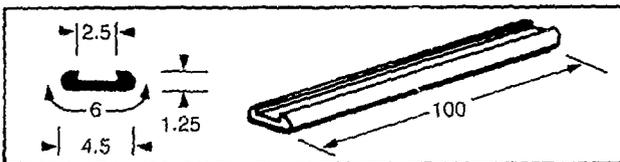
IMPLANTS FOR SCLERAL BUCKLING



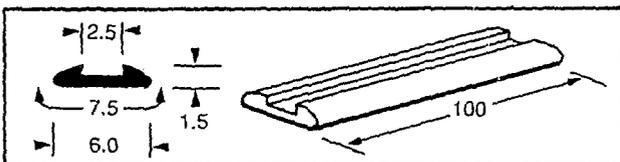
E5381-740



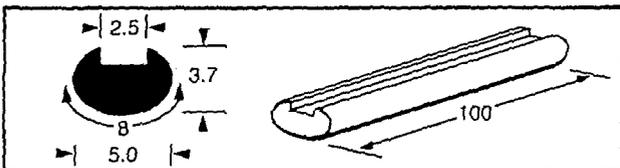
E5381-640



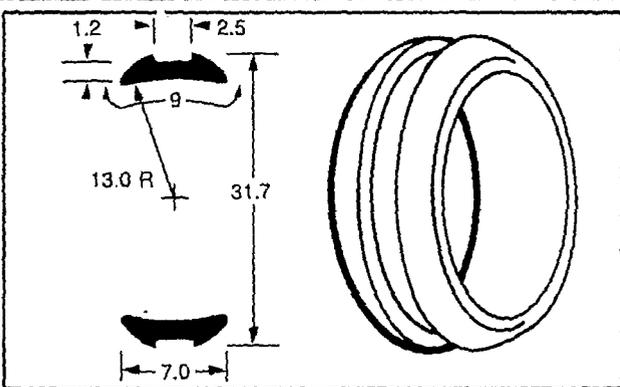
E5381-710



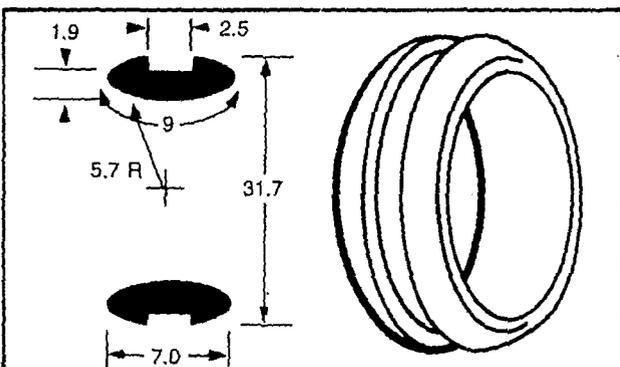
E5381-711



E5381-712



E5381-720



4 E5381-721

SILICONE BOAT

Storz offers two silicone boats which are placed under tantalum clips to help protect the sclera from erosion.

E5381-740

Silicone Boat (260-Style)

Used with Double Tantalum Clip (E5381-852).

E5381-640

Silicone Boat (60-Style)

Used with Single Tantalum Clip (E5381-853).

GROOVED IMPLANTS FOR E5381-700 CIRCLING BAND (240-Style)

Storz offers three silicone strips and six silicone tires to be used in conjunction with the E5381-700 Circling Band (240-Style).

SILICONE STRIPS

E5381-710

Silicone Strip (219-Style)

Indications: narrow scleral bed.

E5381-711

Silicone Strip (220-Style)

Indications: narrow scleral bed.

E5381-712

Silicone Strip (225-Style)

Indications: when high buckle is required.

SILICONE TIRES

E5381-720

Silicone Tire (277-Style)

Concave inner surface

Indications: wide scleral bed.

E5381-721

Silicone Tire (287-Style)

Convex inner surface.

Indications: where heightened buckle is needed.

*All dimensions are in millimeters. \curvearrowright indicates anteroposterior width of undermined sclera the form will indent.

**GROOVED IMPLANTS FOR
E5381-700 CIRCLING BAND
(240-Style) CONTINUED**

E5381-722
Asymmetrical Tire (276-Style)
Asymmetrical concave inner surface.
Indications: wide scleral bed.

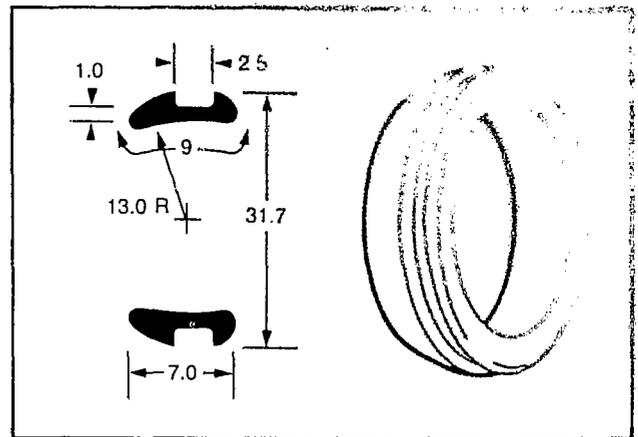
E5381-723
Silicone Tire (279-Style)
Concave inner surface.
Indications: wide scleral bed.

E5381-724
Silicone Tire (280-Style)
Asymmetrical concave inner surface.
Indications: wide scleral bed.

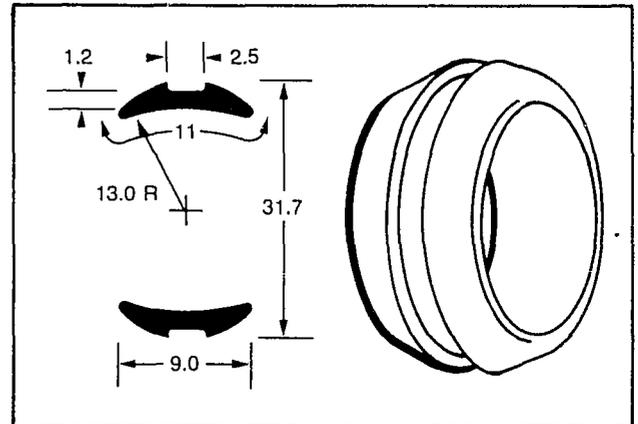
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E5381-725
Silicone Tire (281-Style)
Largest tire.
Indications: massive breaks covering large areas.

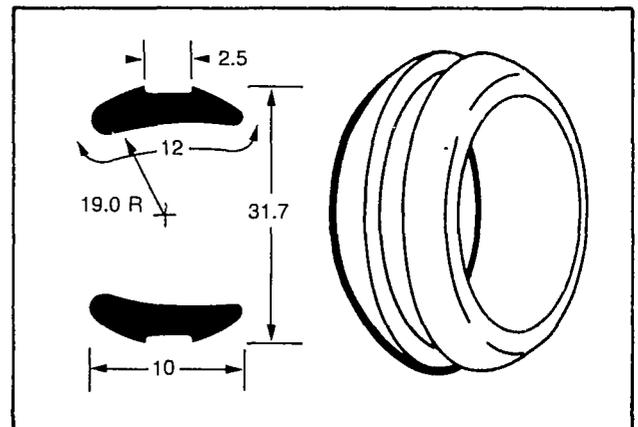
IMPLANTS FOR SCLERAL BUCKLING



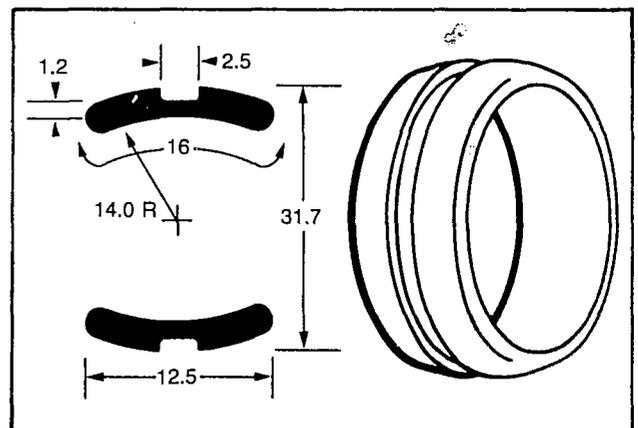
E5381-722



E5381-723



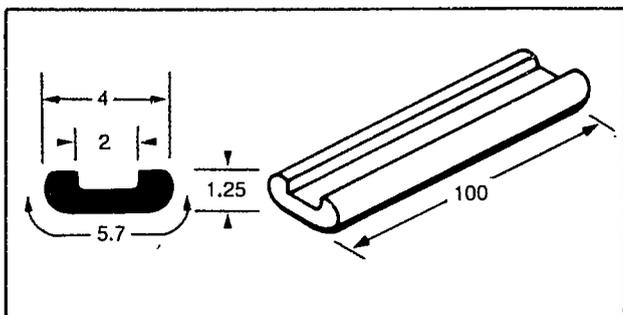
E5381-724



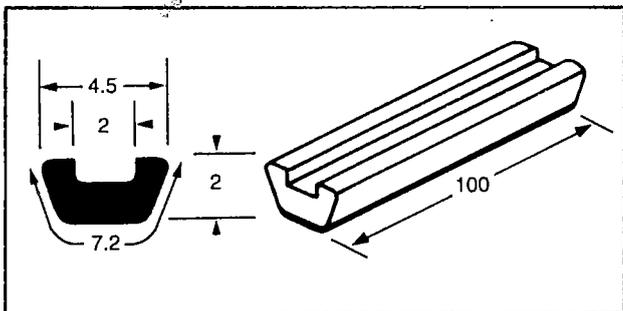
E5381-725

*All dimensions are in millimeters. \curvearrowright indicates anteroposterior width of undermined sclera the form will indent.

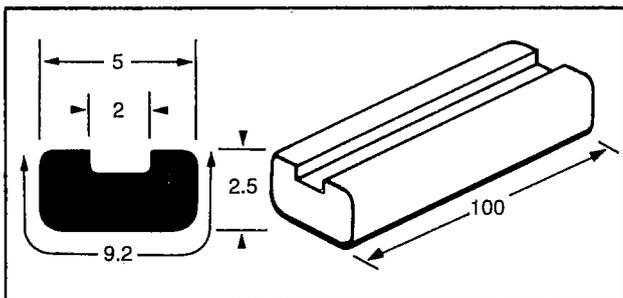
IMPLANTS FOR SCLERAL BUCKLING



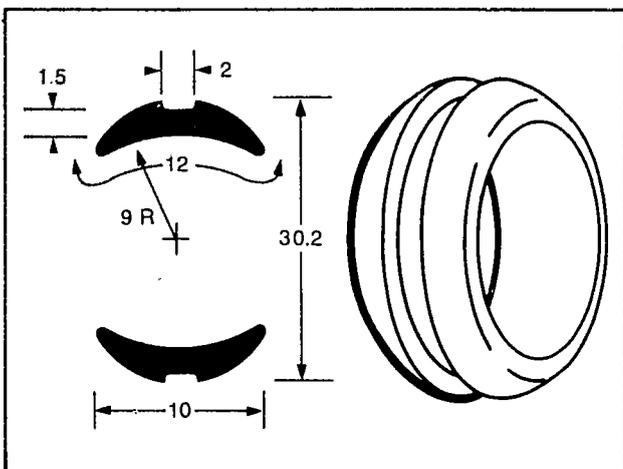
E5381-610



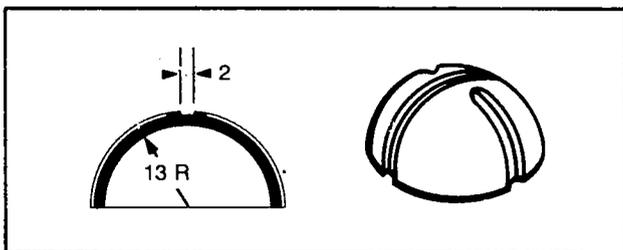
E5381-611



E5381-612



E5381-620



6 E5383-630

GROOVED IMPLANTS FOR E5381-600 CIRCLING BAND (40-Style)

Storz offers three silicone strips, one tire, and one hemisphere to be used in conjunction with the E5381-600 Circling Band (40-Style).

SILICONE STRIPS

E5381-610

Silicone Strip (20-Style)

Indications: narrow scleral bed.

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E5381-611

Silicone Strip (31-Style)

Indications: narrow scleral bed.

E5381-612

Silicone Strip (32-Style)

Indications: narrow scleral bed.

SILICONE TIRE

E5381-620

Silicone Tire (78-Style)

Concave inner surface.

Indications: wide scleral bed.

SILICONE HEMISPHERE

E5383-630

Silicone Hemisphere (77-Style)

Indications: massive retinal breaks.

*All dimensions are in millimeters. indicates anteroposterior width of undermined sclera the form will indent.

IMPLANTS FOR SEGMENTAL BUCKLE

E5381-800

Silicone Strip (41-Style)

Ungrooved. Indications: permanent strip for trapdoor procedure.

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E5381-801

Silicone Strip (42-Style)

Ungrooved. Indications: permanent strip for trapdoor procedure.

IMPLANTS THAT PROVIDE ADDITIONAL BUCKLING

E5381-860

Silicone Button (22-Style)

Indications: used under Silicone Strips E5381-610, E5381-710 and E5381-611 to create a higher buckle.

E5381-871

Meridional Implant (103-Style)

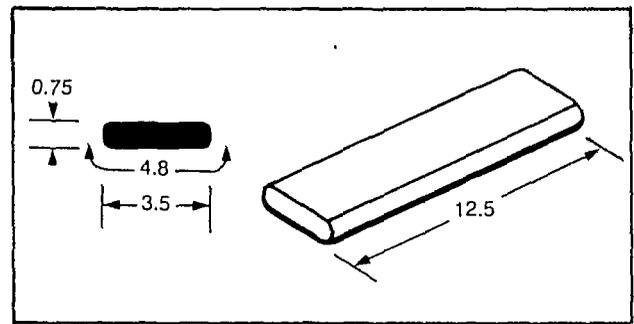
Indications: used under curved implants to provide an additional buckle in the meridional direction.

E5381-870

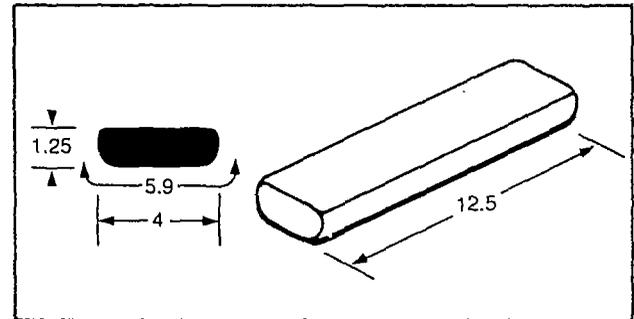
Meridional Implant (106-Style)

Indications: used under curved implants to provide an additional buckle in the meridional direction.

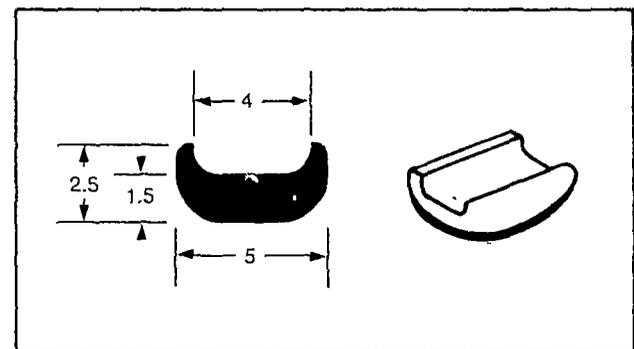
IMPLANTS FOR SCLERAL BUCKLING



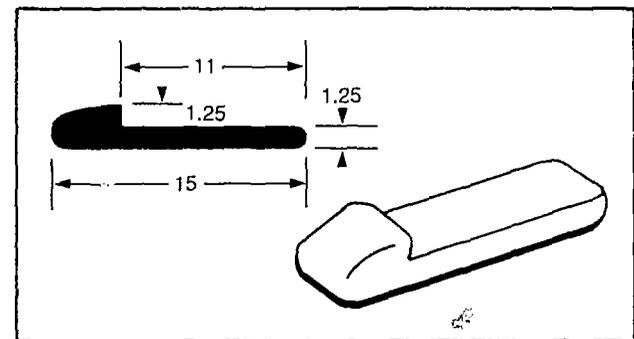
E5381-800



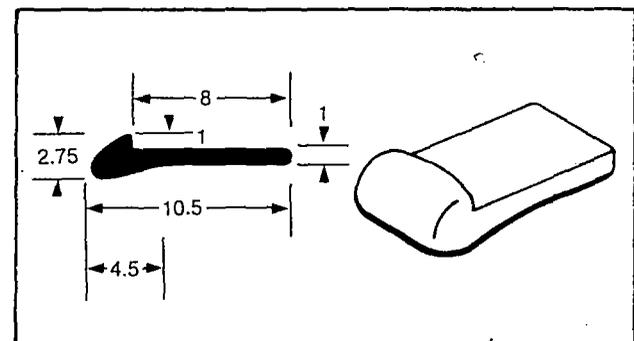
E5381-801



E5381-860



E5381-871

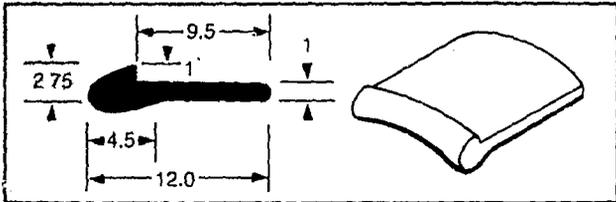


E5381-870

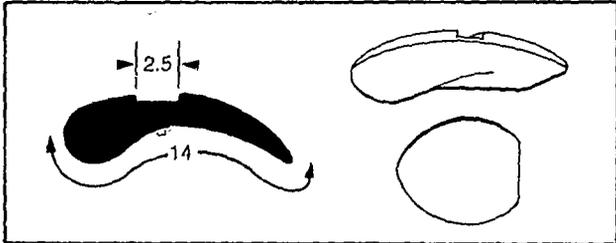
*All dimensions are in millimeters. \curvearrowright indicates anteroposterior width of undermined sclera the form will indent.

IMPLANTS FOR SCLERAL BUCKLING

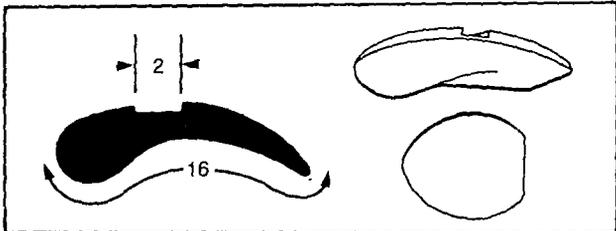
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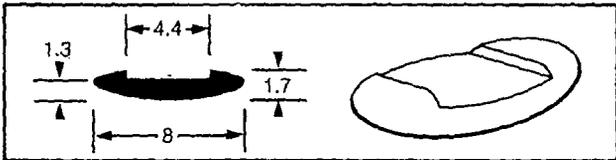
E5381-872



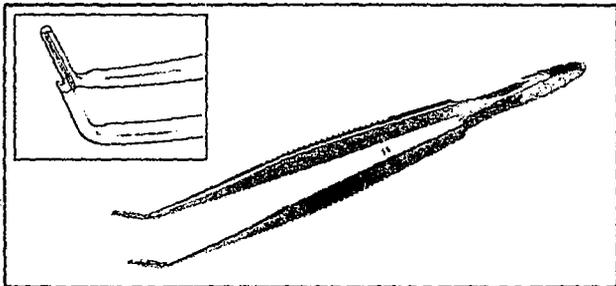
E5381-750



E5381-650



E5381-861



E1892-S

E5381-872

Curved Meridional Implant (112-Style)

Indications: used under curved implants to provide an additional buckle in the meridional direction.

WEDGES

E5381-750

Wedge (137-Style)

Indications: used in conjunction with the E5381-700 Circling Band to provide heightened buckling.

E5381-650

Wedge (135-Style)

Indications: used in conjunction with the E5381-600 Circling Band to provide heightened buckling.

E5381-861

Silicone Pad (80-Style)

Indications: for closing scleral ruptures.

*All dimensions are in millimeters. ↷ indicates anteroposterior width of undermined sclera the form will indent.

SCHATZ ANGLED TYING FORCEPS

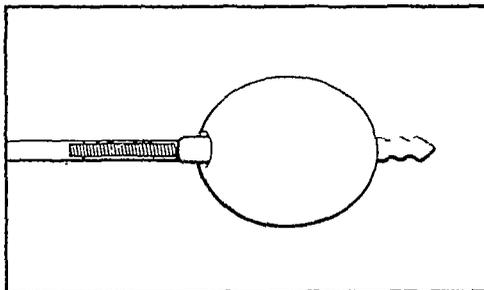
The E1892-S Schatz angled tying utility forceps was developed for retinal reattachment surgery. The angled end allows an easy grasp of silicone banding and buckling material.

LINCOFF RETINAL IMPLANTS

**SCLERAL BUCKLING BALLOON
CATHETER (LINCOFF DESIGN)
E5365**

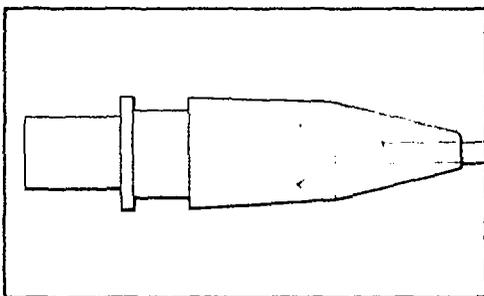
A new implant, developed by Dr. Harvey Lincoff, for treating retinal detachments with breaks not exceeding 6mm. Packaged sterile 3 per box.

- Fewer implant complications
- More rapid visual acuity recovery
- Avoids scleral erosion problems
- Local anesthesia
- No infection or diplopia
- Packaged sterile

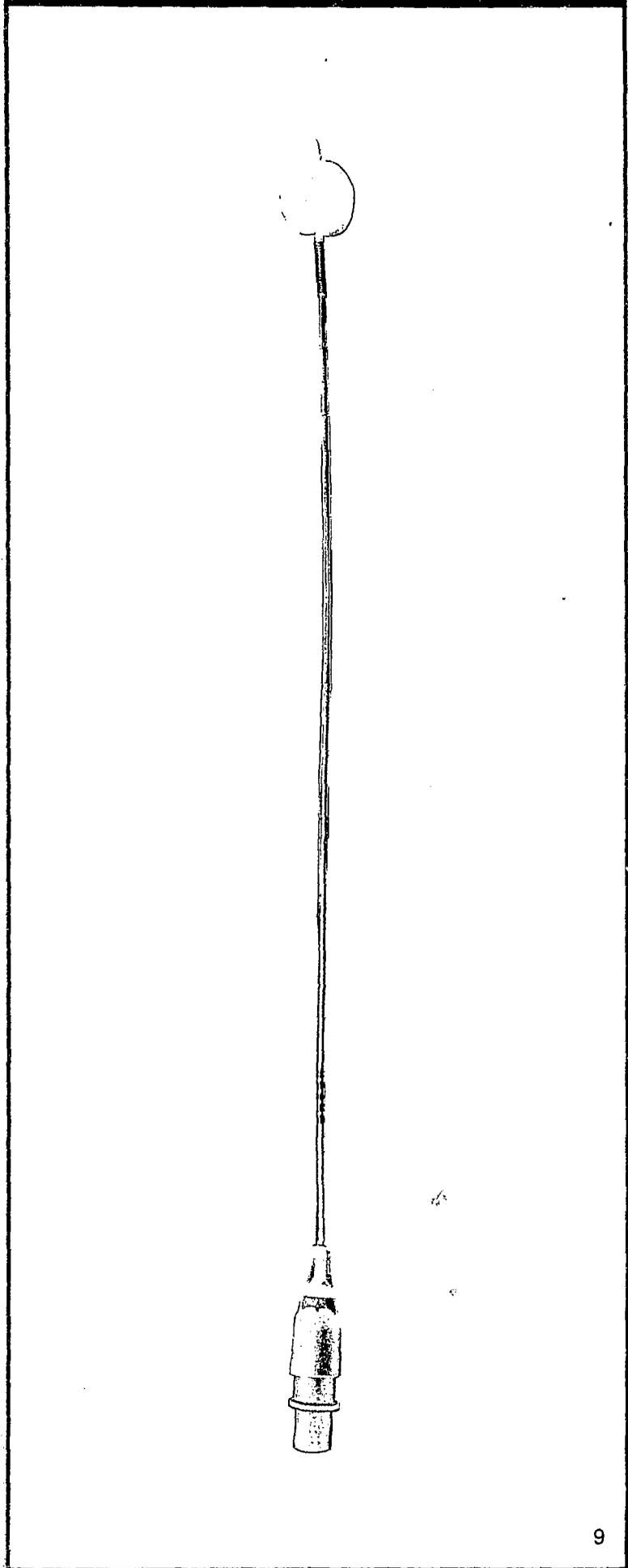


Inflatable balloon is of siliconized latex construction. This provides the strength of latex and the tissue inertness of silicone. The balloon and catheter are 1.2mm in diameter. Total length is 17cm.

A flexible spring is mounted on the catheter to provide stiffness to facilitate ease of insertion into tenon's space.



Valve on proximal end allows easy injection of normal saline to inflate and deflate balloon.



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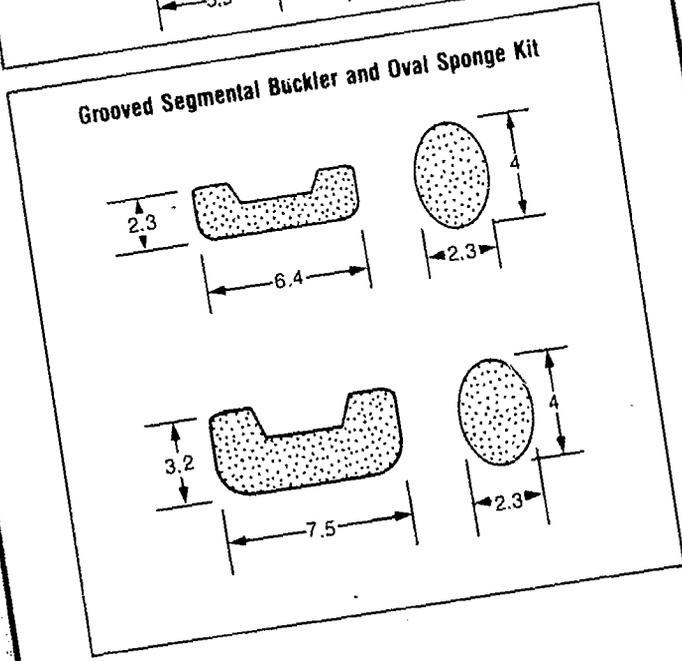
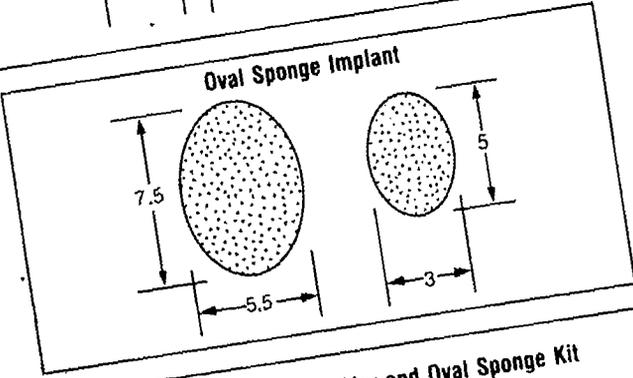
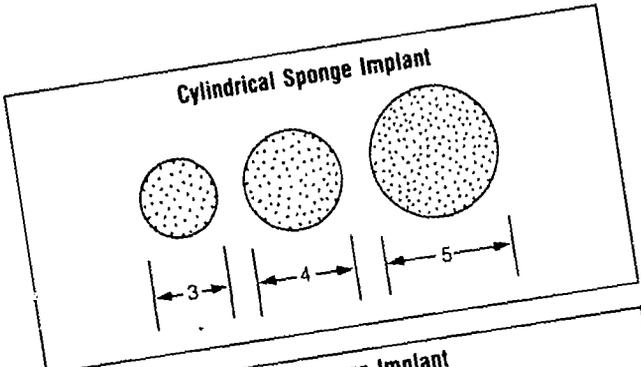
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LINCOFF RETINAL IMPLANTS

LINCOFF SCLERAL SPONGE II

E5395 (1-7)
 Lincoff Scleral Sponge II (Dow-Corning®)
 A soft silicone sponge designed for external scleral buckling of patients with retinal detachments. Available in the following sizes:

Cat. No.	Quantity	Size
E5395-1	5	3mm x 8cm
E5395-2	5	4mm x 8cm
E5395-3	5	5mm x 8cm
E5395-4	5	5.5mm x 7.5mm x 8cm
E5395-5	5	3mm x 5mm x 10cm
E5395-6	5 kits	2.3mm x 6.4mm-groove
E5395-7	5 kits	2.3mm x 4.0mm-oval
		3.2mm x 7.5mm-groove
		2.3mm x 4.0mm-oval

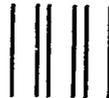


Please send me the following Storz® Implants for Retinal Detachment Surgery.

QTY (BXS)	CAT. NO.	STYLE	DESCRIPTION	QTY (BXS)	CAT. NO.	STYLE	DESCRIPTION
	E5381-				E5381-		
___	600	40	Circling Band	___	800	41	Silicone Strip
___	610	20	Silicone Strip	___	801	42	Silicone Strip
___	611	31	Silicone Strip	___	850	70	Sleeve
___	612	32	Silicone Strip	___	851	270	Sleeve
___	620	78	Silicone Tire	___	852	250	Dbl Tatal Clip
___	630	77	Hemisphere	___	853		Dbl Tatal Clip
___	640	60	Silicone Boat	___	854		Sing Tatal Clip
___	650	135	Silicone Wedge	___	860	22	Silicone Button
___	700	240	Circling Band	___	861	80	Silicone Pad
___	710	219	Silicone Strip	___	870	106	Meridional Implant
___	711	220	Silicone Strip	___	871	103	Meridional Implant
___	712	225	Silicone Strip	___	872	112	Meridional Implant
___	720	277	Silicone Tire	___	E5365		Lincolf Scleral
___	721	287	Silicone Tire				Buckling Balloon
___	722	276	Asymm. Tire	___	E5395 1		Cylin. Sponge 3mm
___	723	279	Silicone Tire	___	E5395 2		Cylin. Sponge 4mm
___	724	280	Asymm. Tire	___	E5395 3		Cylin. Sponge 5mm
___	725	281	Silicone Tire	___	E5395 4		Oval Sponge 7.5mm
___	740	260	Silicone Boat	___	E5395 5		Oval Sponge 3mm
___	750	137	Silicone Wedge	___	E5395 6		Buckler/Sponge Kit
___	E1892-S		Shatz Forcep	___	E5395 7		Buckler/Sponge Kit

Name _____ Title: _____
 Hospital or Clinic: _____
 Shipping Address: _____
 City: _____ City: _____
 Zip: _____ Telephone: _____
 Bill to: _____
 Purchase Order No.: _____

ATTN. DEPT. JG

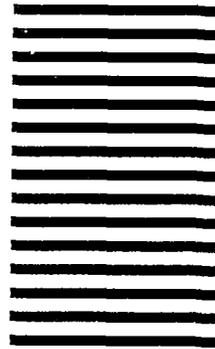


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QTY (BXS)	CAT. NO.	STYLE	DESCRIPTION	QTY (BXS)	CAT. NO.	STYLE	DESCRIPTION
	E5381-				E5381-		
___	600	40	Circling Band	___	800	41	Silicone Strip
___	610	20	Silicone Strip	___	801	42	Silicone Strip
___	611	31	Silicone Strip	___	850	70	Sleeve
___	612	32	Silicone Strip	___	851	270	Sleeve
___	620	78	Silicone Tire	___	852	250	Dbl Tatal Clip
___	630	77	Hemisphere	___	853		Dbl Tatal Clip
___	640	60	Silicone Boat	___	854		Sing Tatal Clip
___	650	135	Silicone Wedge	___	860	22	Silicone Button
___	700	240	Circling Band	___	861	80	Silicone Pad
___	710	219	Silicone Strip	___	870	106	Meridional Implant
___	711	220	Silicone Strip	___	871	103	Meridional Implant
___	712	225	Silicone Strip	___	872	112	Meridional Implant
___	720	277	Silicone Tire	___	E5365		Lincoff Scleral
___	721	287	Silicone Tire				Buckling Balloon
___	722	276	Asymm. Tire	___	E5395 1		Cylin. Sponge 3mm
___	723	279	Silicone Tire	___	E5395 2		Cylin. Sponge 4mm
___	724	280	Asymm. Tire	___	E5395 3		Cylin. Sponge 5mm
___	725	281	Silicone Tire	___	E5395 4		Oval Sponge 7.5mm
___	740	260	Silicone Boat	___	E5395 5		Oval Sponge 3mm
___	750	137	Silicone Wedge	___	E5395 6		Buckler:Sponge Kit
___	E1892-S		Shatz Forcep	___	E5395 7		Buckler:Sponge Kit

Name _____ Title: _____
 Hospital or Clinic: _____
 Shipping Address: _____
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 Purchase Order No.: _____

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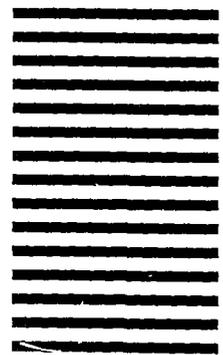
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Implants for Retinal Detachment Surgery Reference Table

IMPLANTS FOR SCLERAL BUCKLING

CATALOGUE NUMBER	STYLE	DESCRIPTION
E5381-600	40	Circling Band 2.0mm wide
E5381-610	20	Strip 2.0mm groove, 5.7mm antero. width
E5381-611	31	Strip 2.0mm groove, 7.2mm antero. width
E5381-612	32	Strip 2.0mm groove, 9.2mm antero. width
E5381-620	78	Tire 2.0mm groove, 12.0mm antero. width, concave inner surface
E5381-630	77	Silicone Hemisphere, 2.0mm groove, 13mm radius
E5381-640	60	Boat 2.0mm groove used with Tantalum Clip E5381-853
E5381-650	135	Wedge 2.0mm groove, 16.0 antero. width
E5381-700	240	Circling Band 2.5mm wide
E5381-710	219	Strip 2.5mm groove, 6.0mm antero. width
E5381-711	220	Strip 2.5mm groove, 7.5mm antero. width
E5381-712	225	Strip oval, 2.5mm groove, 8.0mm antero. width
E5381-720	277	Tire 2.5mm groove, 9.0mm antero. width, concave inner surface
E5381-721	287	Tire 2.5mm groove, 9.0mm antero. width, convex inner surface
E5381-722	276	Asymmetrical Tire, 2.5mm groove, 9.0mm antero. width, concave inner surface
E5381-723	279	Tire, 2.5mm groove, 11.0mm antero. width, concave inner surface
E5381-724	280	Asymmetrical Tire 2.5mm groove, 12.0mm antero. width, concave inner surface
E5381-725	281	Tire, 2.5mm groove, 16.0mm antero. width, concave inner surface
E5381-740	260	Boat 2.4mm groove, used with Tantalum Clip E5381-852
E5381-750	137	Wedge 2.5mm groove, 14.0mm antero. width
E5381-800	41	Smooth Strip 3.5mm wide, 4.8mm antero. width, 12.5mm length
E5381-801	42	Smooth Strip 4.0mm wide, 5.9mm antero. width 12.5mm length
E5381-850	70	Sleeve 1mm inside diameter 30mm length
E5381-851	270	Sleeve .76mm inside diameter 30mm length
E5381-852	250	Double Tantalum Clip for 240 style strip
E5381-860	22	Silicone Button 4.0mm groove
E5381-861	80	Silicone Pad, 4.4mm groove width 8.0mm wide
E5381-870	106	Curved Meridional Implant 10.5mm length
E5381-871	103	Meridional Implant 15mm length
E5381-872	112	Curved Meridional Implant 12mm length
E5381-853		Double Tantalum Clip for 40 style band
E5381-854		Single Tantalum Clip for 40 style band

SCLERAL BUCKLING BALLOON CATHETER (LINCOFF DESIGN)

E5365 Inflatable siliconized latex balloon 17cm length 1.2mm diameter

SCLERAL SPONGE II RETINAL IMPLANTS (LINCOFF DESIGN)

E5395-1	Cylindrical Sponge Implant 3mm x 8cm
E5395-2	Cylindrical Sponge Implant 4mm x 8cm
E5395-3	Cylindrical Sponge Implant 5mm x 8cm
E5395-4	Oval Sponge Implant 7.5mm x 5.5mm x 8cm
E5395-5	Oval Sponge Implant 3mm x 5mm x 10cm
E5395-6	Grooved Segmental Buckler and Oval Sponge Kit 2.3mm x 6.4mm-groove; 2.3mm x 4.0mm oval
E5395-7	Grooved Segmental Buckler and Oval Sponge Kit 3.2mm x 7.5mm-groove; 2.3mm x 4.0mm oval

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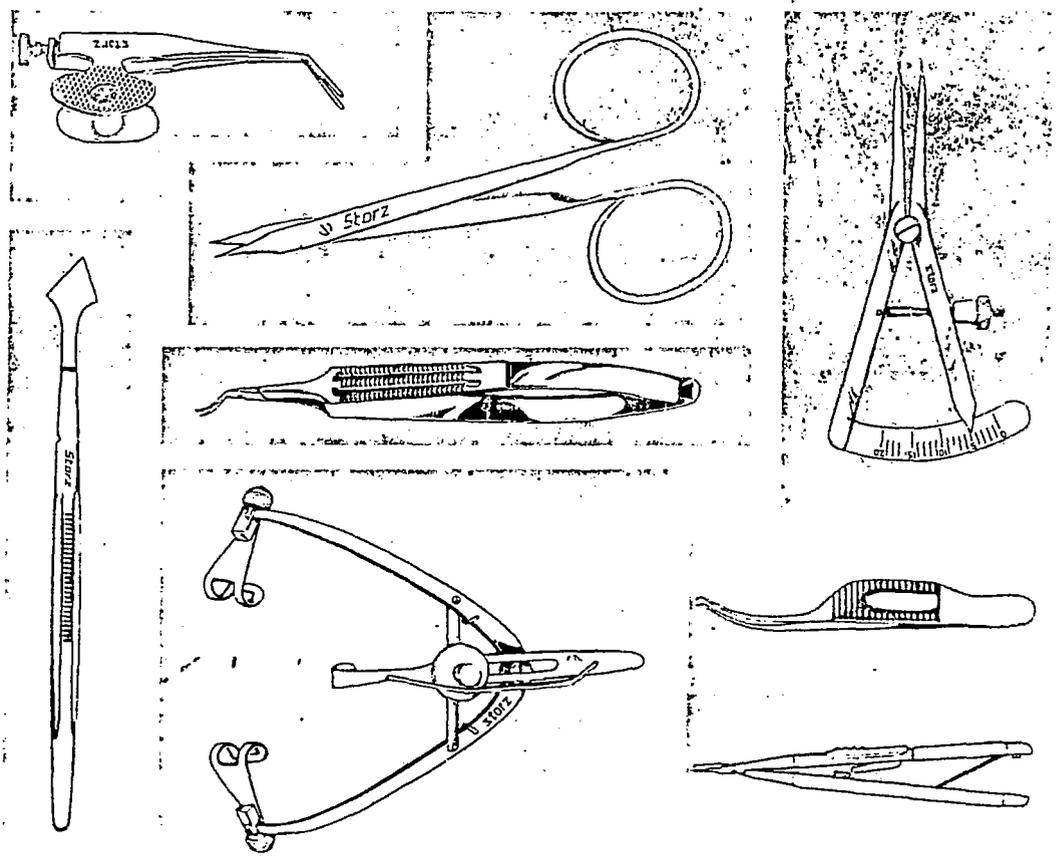
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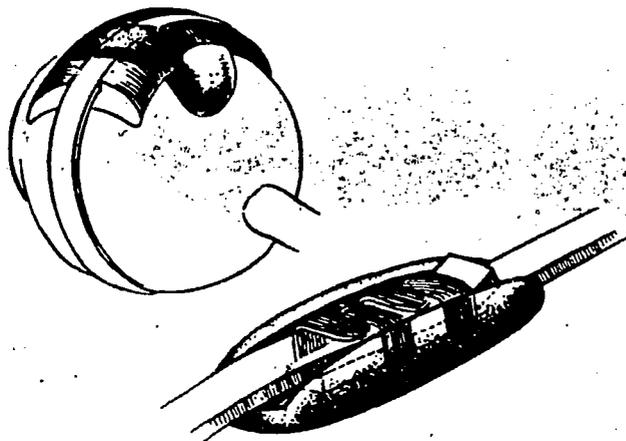
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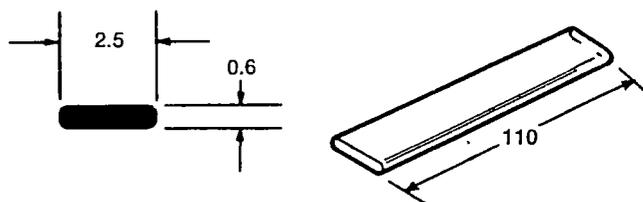


200 SERIES IMPLANTS

IMPLANTS FOR SECURING ENDS OF CIRCLING BAND E-5381-240

The Double Tantalum Clip E-5381-250 secures the overlapped ends of the Circling Band E-5381-240. Two-step closure is possible. First, the clip is partially closed enabling the surgeon to adjust the tension of the circling band. When optimum tension has been obtained, the clip is closed completely. The Clip Forceps E-5379 is available for holding the double clip while the ends of the circling band are positioned and the clip is closed.

The Silicone Boat E-5381-260 is used as a scleral pad under the clip to avoid the possibility of scleral erosion.



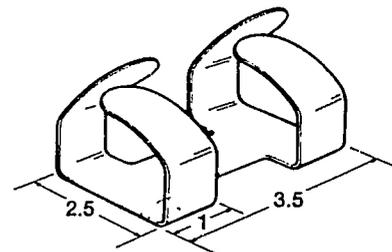
★E-5381-240 Band, Circling. ●

IMPLANTS FOR RETINAL DETACHMENT SURGERY

The scleral buckling procedure has proved useful in reattaching the retina to the choroid. A buckle is formed by a silicone or gelatin implant in the sclera.

Implants for both encircling and segmental buckles have been used and tested over a ten year period. In order to be most effective, these implants are designed to be:

- Soft and elastic
- Nontoxic
- Nonantigenic
- Easy to mold
- Easy to shape by the surgeon
- Sterile or readily sterilizable



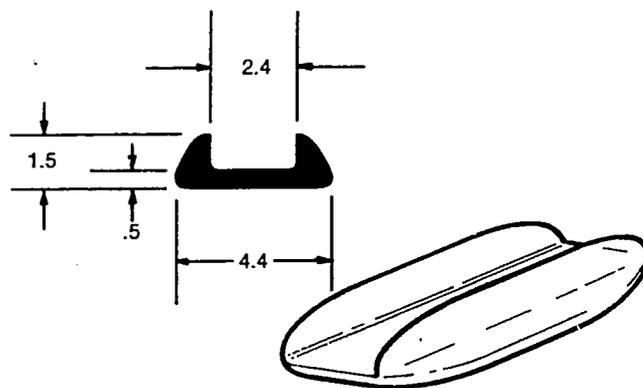
E-5381-250 Clip, Tantalum: double. ●

ENCIRCLING BUCKLE

Grooved silicone implants are held in place by a silicone circling band around the globe. Several different implants, varying in size and shape, may be adapted under the circling band. The precise buckle, suited to a particular case, may be obtained with minimum trimming of the implant, or with a combination of implants, under the circling element.

Two circling bands are available. The Circling Band E-5381-40 has the correct tensile strength for maintaining an implant in position with sufficient pressure to form a permanent buckle and minimize scleral erosion. The more recent Circling Band E-5381-240 has the same cross section and therefore the same tensile strength. It is also wider and flatter; this reduces scleral indentation where indentation is not desired and also reduces the danger of late erosion.

A special series of implants has been designed for use with each of the two circling bands. Implants in the "200 Series" fit under the Circling Band E-5381-240 and implants in the "Sub-100 Series" fit under the Circling Band E-5381-40.



E-5381-260 Boat, Silicone. ●

★ Designates most popular model or size.

● AUTOCLAVE ▲ GAS ■ SOLUTIONS ◆ DRAPE

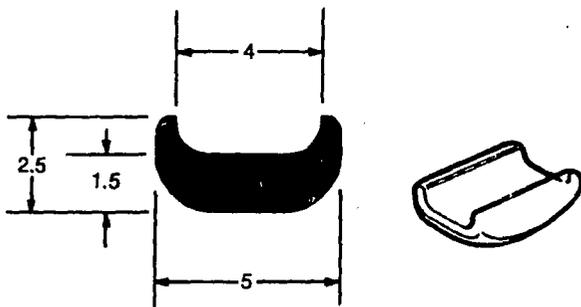


ADDITIONAL IMPLANTS FOR THE 200 AND SUB-100 SERIES

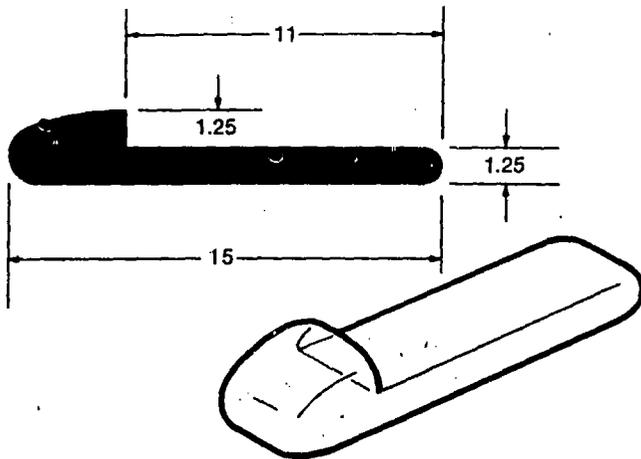
Three non-grooved silicone implants are used under the grooved implants to create additional buckling of the sclera.

The Button E-5381-22 fits under the Strips E-5381-219, E-5381-20 and E-5381-31 to effect a localized heightening of the buckle. If one button is not long enough in the equatorial direction, two buttons can be cut transversely and apposed to form an additional implant 8mm long.

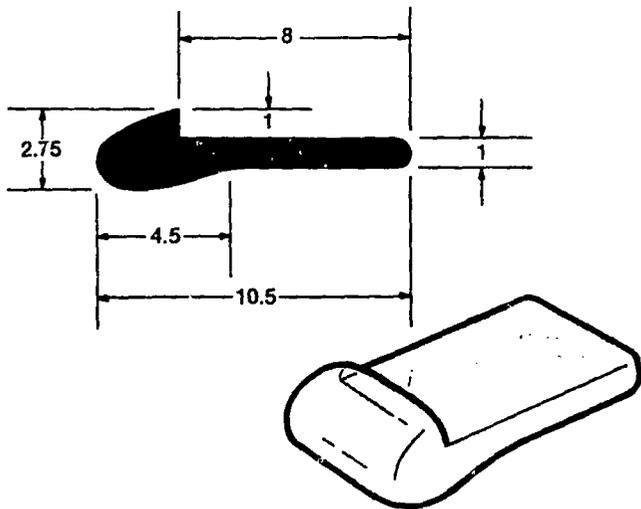
The Meridional Implants E-5381-103 and E-5381-106 are used under any grooved implant and particularly under a curved implant (tire or hemisphere) for additional buckling in a meridional direction.



E-5381-22 Button, Silicone. ●



E-5381-103 Implant, Meridional. ●

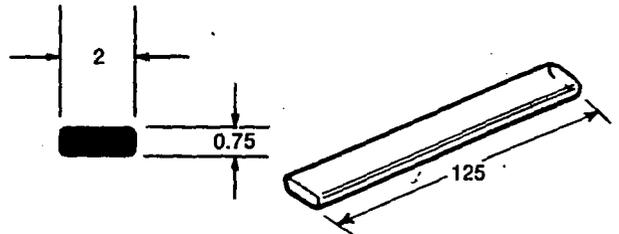


E-5381-106 Implant, Meridional. ●

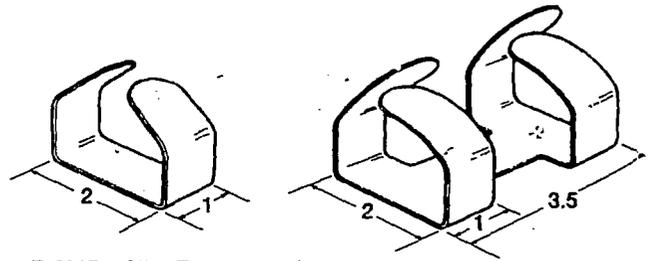
SUB-100 SERIES IMPLANTS IMPLANTS FOR SECURING ENDS OF CIRCLING BAND E-5381-40

One Double Tantalum Clip E-5388 or two Single Tantalum Clips E-5387 will secure the overlapped ends of the Circling Band E-5381-40. Two-step closure is possible. First, the clip(s) (are) partially closed enabling the surgeon to adjust the tension of the circling band. When optimum tension has been obtained the clip(s) is (are) closed completely.

The Silicone Boat E-5381-60 is used as a scleral pad under the clip to avoid the possibility of scleral erosion.

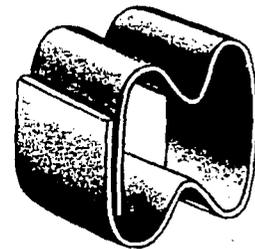


★E-5381-40 Band, Circling. ●

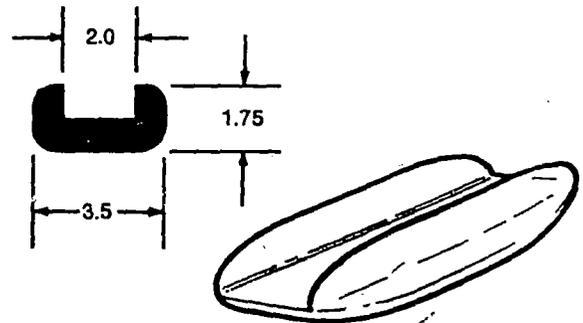


E-5387 Clip, Tantalum: single. ●

★E-5388 Clip, Tantalum: double. ●



E-5386 Clip, Tantalum, FRIEDMAN: double barrel tubular, 2mm long. ●



E-5381-60 Boat, Silicone. ●

★ Designates most popular model or size.

● AUTOCLAVE ▲ GAS ■ SOLUTIONS ◆ DRAPE

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