CHEMETRON Medical Division
Allied Healthcare Products, Inc.

PURCHASE SPECIFICATION

TITLE OPERATING INSTRUCTION
GOMCO CIRCUMCISION CLAMP

PART NO. S168-194-001

SHEET 1 OF 12

Manufacturer must conform with this specification, and any change in the product supplied under this specification must receive prior approval of Chemetron Medical Products Division.

RELEASE # N3182

REV. E ECO# 12388

FORM: 21-00-3000
ENGR #: S168-194-001
REV. E

OPERATING INSTRUCTIONS

GOMCO® CIRCUMCISION CLAMP

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INSTRUMENTS OF CARE

(E)

AHP STORES

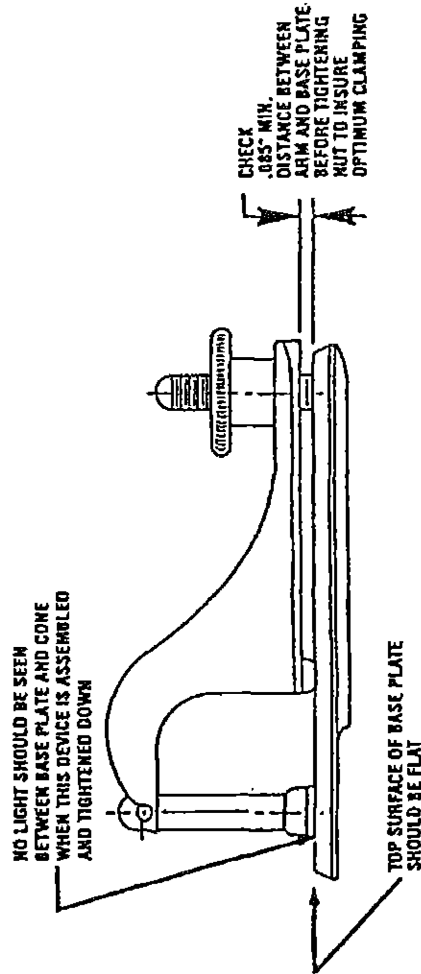
PRECAUTIONS

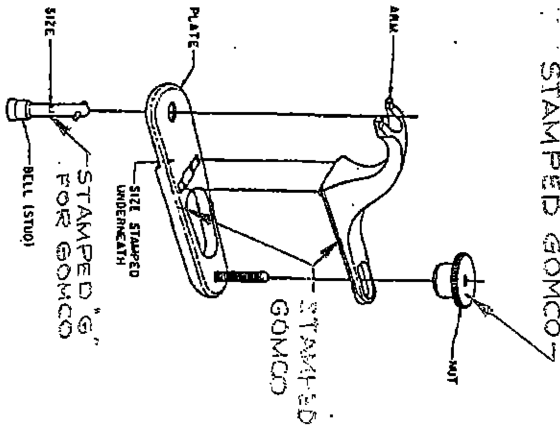
Warnings: Indicates situations where patient or operator injury may occur if described procedures are not followed.
Cautions: Indicates situations where equipment damage may occur if described procedures are not followed.

WARNINGS

- This clamp must never be used in conjunction with electrocautery or laser surgical procedures.
- Circumcision clamp must be disassembled and sterilized before each use.
- This clamp must never be used if component parts are damaged, missing, clearly worn or the assembled device does not perform as described.
- Prior to each use, always insure that plate and bell (stud) are the same size.
- Prior to initiating the surgical procedure you must insure that expected clamping function has been properly achieved.
- Use only component parts manufactured by "Gomco" when assembling this device.

IMPORTANT: Some bleeding may occur and/or some sutures may be required depending on the prescribed surgical technique.



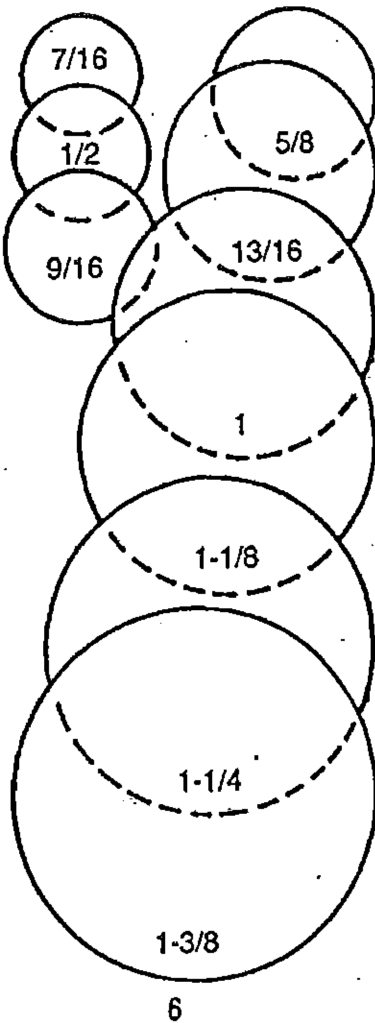


STERILIZATION
MAX. TEMP. 250°F (B)

The Gomco Circumision Clamp must be sterilized before using. This should be done by following the sterilization procedure for surgical instruments recommeded by the manufacturer of your sterilizer.

SIZE SELECTION:

CATALOG NO.	DESCRIPTION	BOTTOM FLARE CONE DIAMETER GLANS DIA. METRIC (cm)	ENGLISH (inches)
02-00-500	Ex. Small	1.10	7/16
02-01-500	Newborn	1.30	1/2
02-02-501	Infant	1.45	9/16
02-03-501	Child	1.60	5/8
02-04-502	Youth	2.10	13/16
02-05-503	Adult	2.60	1
02-06-504	Adult	2.90	1-1/8
02-07-505	Adult	3.20	1-1/4
02-08-506	Adult	3.50	1-3/8



CIRCUMCISION OF THE NEWBORN

The device is properly sized and designed to allow easy negotiation by a single person. Regarding the prescribed surgical technique, it is simple, and requires significantly less time and effort when compared with other available methods. With newborns the clamp generally does not require sutures, rarely produces bleeding, and consistently leaves a clean cut incision which uneventfully heals in 36 hours (as the mucous membrane and skin become securely united).

Figure 1 and Figure 2 depict the procedure, and the required instruments are namely the clamp, two small hemostats, a probe with a flattened end, a scissors with one blunt blade, an abcess knife, sterile vaseline and vaseline gauze.

The recommended procedure is performed as follows:

After proper cleansing of the penis (E) and pubis, the dorsal surface of the prepuce (A) is placed on a stretch by bilateral engagement of the median line with a pair of hemostats. A flat probe is subsequently lubricated and pressed between the prepuce and glans to separate the adherent mucous membrane from the prepuce. The prepuce is then gently retracted exposing the full glans penis (E). Once again, the organ is cleansed and prepped accordingly. In those cases where the prepuce is drawn tightly over the glans a partial dorsal slit will often facilitate application of the cone portion of the draw stud over the glans (it should be noted, that should the slit be excessively long the cone will have a tendency to slide off the glans). Ideally the incision should be made just long enough for the

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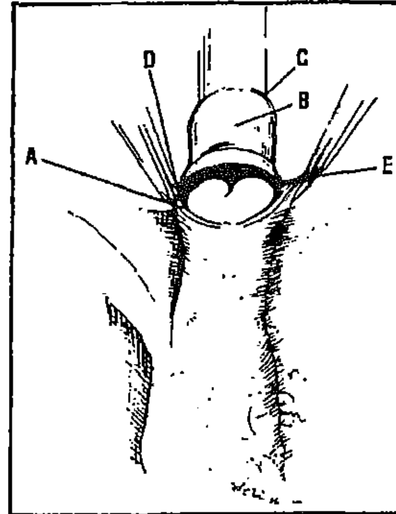

FIGURE 1

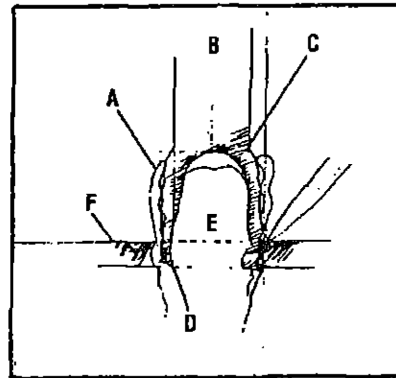

FIGURE 2

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cone to be comfortably yet snugly retained). After lubricating the inside of the cone (B), it is placed over the glans penis allowing a sufficient amount of mucous membrane to fit below the cone (in order to preclude the removal of excess tissue).

The prepuce is then pulled through and above the bevel hole in the platform (F) and clamped in place. In this manner the prepuce is crushed against the cone causing hemostasis of the regional blood vessels. We recommend that this pressure remain a full five minutes, and in older children a little longer. The excess of prepuce is then excised with a sharp knife without danger of cutting the glans (which is protected by the cone portion of the device) leaving a fine 1/32 of an inch ribbon-like membrane from the new union of skin and mucous membrane; the pressure is subsequently released. The circumcision is

now completed with the penis wrapped in vaseline gauze. The use of anesthesia is at the discretion of the physician. It should be noted that in children beyond the age of 12 months, we deem it advisable to place a few sutures.

The wounds heal uneventfully and leave a clean and natural appearance.

ADULT CIRCUMCISION

REQUIRED INSTRUMENTS AND SUPPLIES

MEDICATIONS:

(a) Anesthetics: Lidocaine, etc.
(b) Antiseptics: Betadine, etc.
(c) Ointments and topic is for dressing:
    Petrolatum (Sterile)
    Topical anti-bacterial:
        i.e., bacitracin

INSTRUMENTS:

(a) Syringe (for anesthetic injection)
(b) Hemostats
(c) Scissors
(d) Knife
(e) Probe or director
(f) Adult circumcision clamp (Fig. 5)
(g) Thumb forceps (with teeth)
(h) Needle holder

INCIDENTAL SUPPLIES:

(a) Surgical drapes (optional)
(b) Applicators
(c) Sterile gauze pads
(d) Bandage roll and adhesive tape
(e) Sutures (Non absorbable, according to preference)

The adult circumcision clamp is a modified version of the infant instrument. The adult clamp (Figure 1) consists of four basic parts, a cone (A), base plate (B), Arm (C) and Nut (D).

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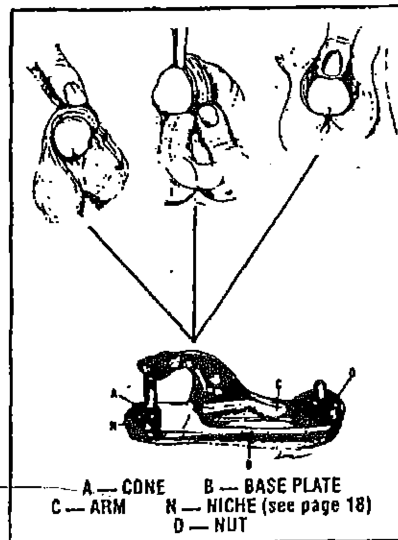

FIGURE 1

The action of the clamp depends on the pressure exerted on a narrow rim of tissue that insures adherence of the outer skin to the inner preputal surface; at the same time preventing immediate retraction of blood vessels.

In slipping the cone over the glans in a trial fitting its applicability may be predetermined.

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In the case where the glans is markedly smaller than the initial cone used, a smaller cone should be tried. Further insight into the use of this device is provided in the foregoing discussion.

ADULT OPERATIVE TECHNIQUE

Once properly positioned on the operating table, the patient's penis (entire shaft and glans) is carefully painted with antiseptic solution and the area is appropriately draped. The method of anesthesia calls for a circular injection in the mid-portion of the shaft (Figure 2); administered into the areolar tissues, since intracutaneous injection is virtually impossible in this region. As a rule of thumb 2.5 cc will usually suffice. The foreskin is then retracted with the introduction of

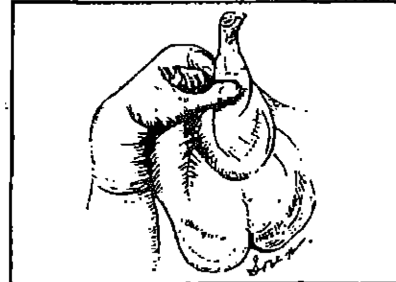

FIGURE 2

anesthetic infiltrated about the corona toward the base of the glans. During this step particular care should be taken to avoid the use of excessive anesthetic which poses the threat of distortion of the part. This type anesthetic ring completely encircles

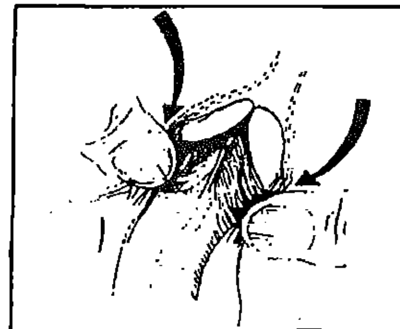

FIGURE 3

the glans (the frenum must also be carefully infiltrated in order to avoid intra-operative pain.)

In the case of an unretractable foreskin a line of infiltration is made dorsally, precisely in the mid-line zone (Figure 3A). Ideally the anesthetic should be deposited close to the preputial surface. A dorsal incision is made (Figure 3B) with sufficient length to allow full retraction (if excessively long the cone will not maintain its correct placement). Bleeders commonly encountered along the severed edge should be ligated in order to prevent occlusion of the oper-

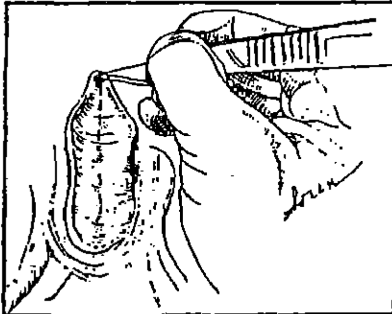

FIGURE 3A

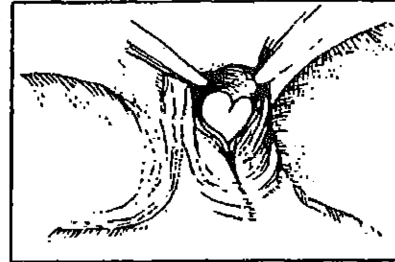

FIGURE 3B

ative field. Following this incision, the usual coronal injection is carried out.

All adhesions are then separated by either blunt or sharp dissection. In the next step the cone is lubricated with petrolatum on the inner and outer surfaces and then slipped over the glans and adjusted, so that the free end of the frenum is on a level with the rim of the cone (Figure 4).

The next step involves the "picking up" of the redundant tissue at the exact junction of the outer skin and preputial surface; this is best accomplished with hemostats placed anteriorly,

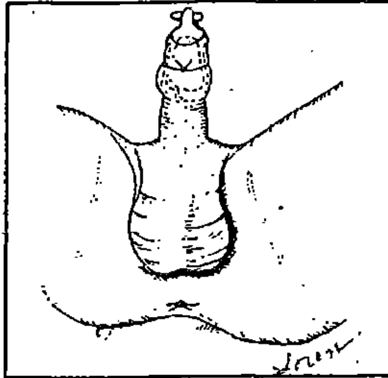

FIGURE 4

posteriorly and laterally. The mass of tissue is then pulled over the cone (if desired, the cone may be applied after the skin has been picked up). The cone is then forced down and the redundant tissue pulled up; caution should be exercised to determine that the frenal relationship of the cone is unaffected. Through applied tension to the tissue, the amount to be removed can be governed. While maintaining relationships, a short piece of #25 gauge annealed copper wire is tied around

the tissue at the level of the niche and tightened snugly (Figure 4). The excess wire is then clipped with the twisted ends bent back against the penis to insure that the portion to be removed can be easily visualized. Since the wire maintains the position of the cone and the tissue, the hemostats are removed and the base plate slipped over the mass. The top plate is hooked under the arms of the cone and slipped into its notch in the base of the plate, with the screw turned down securely. This pressure should be maintained for a full five minutes. A lubricant applied to the penis is often of value should there be difficulty in slipping the base plate over the cone and redundant tissue. The base plate must be below the level of the copper wire and against the flare of the cone.

At the end of the five minutes, the redundant tissue is excised holding the knife parallel to the

surface level of the base plate (Figure 5). Cautions should be exercised in order to insure that the referenced tissue is removed flush with the level of the plate. Following this important maneuver the screw is loosened and the clamp removed. The pressure has thus provided a temporary coaptation of the severed edges with accompanying hemostats. Since neither condition is permanent, considerable care is required when placing the sutures.

The first stitch is a mattress about the frenum (Figure 6). This is followed by the placement of two interrupted sutures bilaterally to complete the trian-

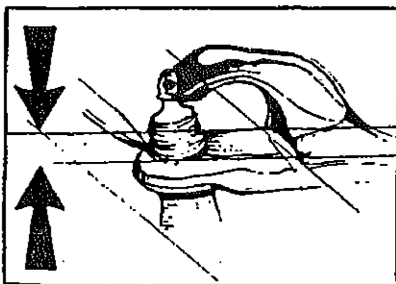

FIGURE 5

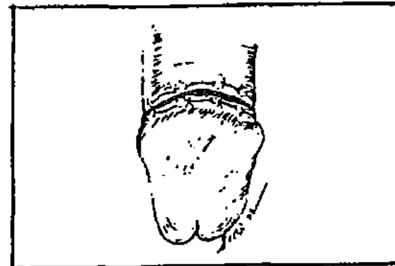

FIGURE 6

gle at the frenum; followed by a mattress suture dorsally (Figure 6A). These sutures in effect control the major bleeding points. To continue, an adequate number of mattress sutures are then placed on either side of these primary sutures to maintain accurate coaptation of the severed edges.

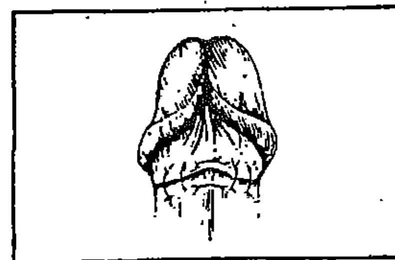

FIGURE 6A

The area is again checked for bleeding, and in its absence a topical antibacterial may be applied to the wound in combination with a simple vaseline dressing.

POST OPERATIVE CARE

Almost without exception there are no unusual complications with this method. Simple daily dressings are applied, with removal of the stitches on approximately the fifth day.

NOTE:
The manufacturer acknowledges the cooperation of Dr. Robert Soren, Medical Surgical Art & Text, 540 N.W. 214th Street, Miami, Florida 33169, in the preparation of this pamphlet.

ORDERING INFORMATION

CATALOG	FOR GLANS DIA.
02-00-0500	Ex. Small 1.1 cm (7/16")
02-01-0500	Newborn 1.3 cm (1/2")
02-02-0501	Infant 1.45 cm (9/16")
02-03-0501	Child 1.6 cm (5/8")
02-04-0502	Youth 2.1 cm (13/16")
02-05-0503	Adult 2.6 cm (1")
02-06-0504	Adult 2.9 cm (1-1/8")
02-07-0505	Adult 3.2 cm (1-1/4")
02-08-0506	Adult 3.5 cm (1-3/8")