Circumcision – Device Solutions

PA’s Device Development Process
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“IT’S HITTING THE RIGHT TARGET THAT COUNTS.”
PA’s Role

- Understand the technical landscape for MC
- Develop high level user and device requirements
- Develop novel concepts for existing procedures and potential new devices
Concept to Production

1. Develop the Concept
   - Requirement Specification
   - Works like

2. Develop the Function
   - Design Specification
   - Works like, Looks like

3. Develop the Form
   - Production Specification
   - Works, looks, & made like

4. Develop the means for production
5. Develop any post-production improvements
6. Clinical trials
7. Release Specification
8. Volume Production

Test Test Test
Hitting the Right Target

What are the things you have to do to be really successful?

**Patient**
- HIV Protection
- Post-op Recovery
- User Acceptance

**Clinician Process**
- Ease of Use
- Procedure Time
- Cut Speed

**Clinician Outcome**
- Safety
- Wound Closure
- Consistency

**Supplier**
- Cost
- Packaging and Distribution
- Field Usability
- Sizeability

(User Requirements Specifications)
# A Device Approach – The Steps Forward

<table>
<thead>
<tr>
<th>Today</th>
<th>Tomorrow</th>
<th>The Future</th>
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<tbody>
<tr>
<td>Save lives immediately</td>
<td>Introduce existing devices</td>
<td>Develop Ideal Approach</td>
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<tr>
<td>Provide training, supplies, doctors, etc. for existing methods of Adult Male circumcisions</td>
<td>Evaluate various necrosing clamps currently on the market and select one or more to pilot in Africa.</td>
<td>Develop two concepts, one an advanced necrosing style clamp and second a temporary clamp with guided closure device.</td>
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Classification of Circumcision Clamping Devices

Forceps Guided Method

- More stitches may be required than with other methods.
- Suturing step is time consuming
Classification of Circumcision Clamping Devices

Temporary Crush – Mogen Clamp

- The glans is not protected.
- Possible to capture glans in clamping device.
- Does not remove as much foreskin as other devices
- For adults suturing is required

Placement of the Mogen clamp

While the Mogen clamp remains closed, the prepuce is excised distal to the clamp.
Classification of Circumcision Clamping Devices

Temporary Crush – Gomco Clamp

- The Gomco Clamp, by its very design, removes a larger portion of the inner foreskin than does the forceps guided or freehand techniques.

- For adults suturing is required
Classification of Circumcision Clamping Devices

Necrosing Device

What is a Necrosing Device?
The foreskin is clamped or tied off, similar to umbilical cord removal.

Remains on the penis for 7 to 10 days until it falls off or is removed.

Disadvantage is the patient must wear this rather large device for 7 to 10 days.

Some manufactures recommend the application of minimal DSSS (Delayed Secondary Superficial Suture) for adults after removal.
Example Necrosing Clamp – Sunathrone Movie

Click Here to see movie
Will any of the current models meet the current needs?

Necrosing Clamps

- Tara Klamp
- Smart Klamp
- Ismail Clamp
- Sunathrone Clamp
- Plastibell
- Kirve Klamp
- Zhenxi Circ Ring

Off The Shelf
# Introduce Existing Devices

### Is there a quick hit already available to use?

### Is a necrosing clamp the answer?

### What are some of the benefits of a Necrosing Clamp?

Note: The claims listed below were provided by the manufacturers on their websites.

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Safer - Protects the glans during circumcision</td>
<td>Avoids cross infections</td>
</tr>
<tr>
<td>Minimal to no bleeding</td>
<td>A clean line of excision; helps to promote rapid healing</td>
</tr>
<tr>
<td>Easy to perform the operation</td>
<td>No special dressings required</td>
</tr>
<tr>
<td>Disposable</td>
<td>No stitching required</td>
</tr>
<tr>
<td>Pre-sterilized</td>
<td></td>
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Sounds Too Good

What are some of the unknowns about Necrosing Clamps?

- How well will they work for Adult Male Circumcision?
- What happens during an erection?
- How long is the clamp required to stay on for an Adult?
- Does the clamp necrose the foreskin and falls off or is a follow-up visit required for removal?
- How many device sizes are required?

- PA’s recommendation is to evaluate various necrosing clamps currently on the market.
- Select one or more to do clinical studies in the African environment.
- An independent study is required to substantiate claims made by the manufacturers.
Develop Ideal Approach

The Goal:

To develop new concepts that will meet the identified needs of the adult MC market in Africa.

The Concept Development Process

1. Understand the current situation
2. Identify the needs
3. Study existing device concepts
4. Develop potential solutions
5. Rank solutions
6. Develop best concepts further
7. Score final concepts

Have identified two promising concepts.
PA’s Concepts

Patient
- HIV Protection
- Post-op Recovery
- User Acceptance

Features/Benefits

Advanced Necrosing Clamp

Control of how much foreskin is removed – Maximum HIV protection

Minimal to no bleeding – Clamping prevents bleeding, only blood is from foreskin

Protective Guard – A cover for cutting area and foreskin to protect staff/patient

Small Clamping Band – Provides user with better post op experience

Light Weight - Provides user with better post op experience

Temporary Clamp with Guided Closure System

Operation Completed at end of visit – Cut and closed

Control of how much foreskin is removed – Maximum HIV protection

Minimal to no bleeding – Temporary Clamp prevents bleeding, only blood is from foreskin
PA’s Concepts

Features/Benefits

**Clinician**

**Outcome**
- Safety
- Ease of Use
- Procedure Time

**Process**
- Wound Closure
- Consistency
- Cut Speed

**Designed for use by lower cadre staff** – Guided procedure

**Faster Operation** – the surgeon can supervise more cases done by other staff

**Disposable** – No need to autoclave device

**Auto-Cut** – Same cut every time, no sharps near patient or staff

**No scalpel required** – No sharp device required

**Consistent results** – Not operator dependent (first cut of the day same as last)

**Interlocks** – Ensures operations happen in proper sequence

**Auto-destruct** – Prevents reuse of device

**Protective Guard** – Cover for cutting area and foreskin to protect staff/patient

**Glans Protection** – Hard protective tube is always in place during device operation
PA’s Concepts

Features/Benefits

Temporary Clamp with Guided Closure System

**Clinician**

**Outcome**
- Safety
- Ease of Use
- Procedure Time

**Process**
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**Designed for use by lower cadre staff** – Guided procedure

**Faster Operation** – the surgeon can supervise more cases done by other staff

**Simple Operation** – Place, Clamp, Cut, Close, Remove

**Disposable &/or Durable** – If supply line is an issue it can be made for either situation

**Consistent results** – Not operator dependent (closures all the same)

**Guided Closure System** – For use with lower cadre staff.

**Protection of Glans** – Protective tube in place during skin closure

**Operation Completed at end of visit** – Cut and closed
Features/Benefits

Supplier
- Cost
- Packaging and Distrib.
- Field Usability
- Sizeability

One Circumcision Kit fits all Adults – Helps reduce supply line issues.

Pre-Sterilized – No sterilization required in the field.


Requires no electricity – no external power source required.

Advanced Necrosing Clamp

One Circumcision Kit fits all – (Disposable Only) Helps reduce supply line issues.

Pre-Sterilized – (Disposable Only) No sterilization required in the field.

Estimated Cost – $15 - $20 for disposable. Durable version would be more.

No need to re-supply Durable Model – Designed to last many years.

Temporary Clamp with Guided Closure System
What are the things to be successful?

- Provide HIV protection
- Ensure Safety
- User Acceptance
- The Right Cost

Estimate purchase price for these new devices is between **$15 to $20.**

(That is for the device only.)
Conclusions and Next Steps

Support clinics immediately with training, logistics, supplies and staffing

Evaluate and select the best “Off the Shelf” device for immediate study and possible deployment.

Start today on the evaluation and development of a potential new device solution