

*“It’s hitting the right target  
that counts.”*

# Circumcision – Device Solutions

PA’s Device Development  
Process

Dan Walsh, John Gola

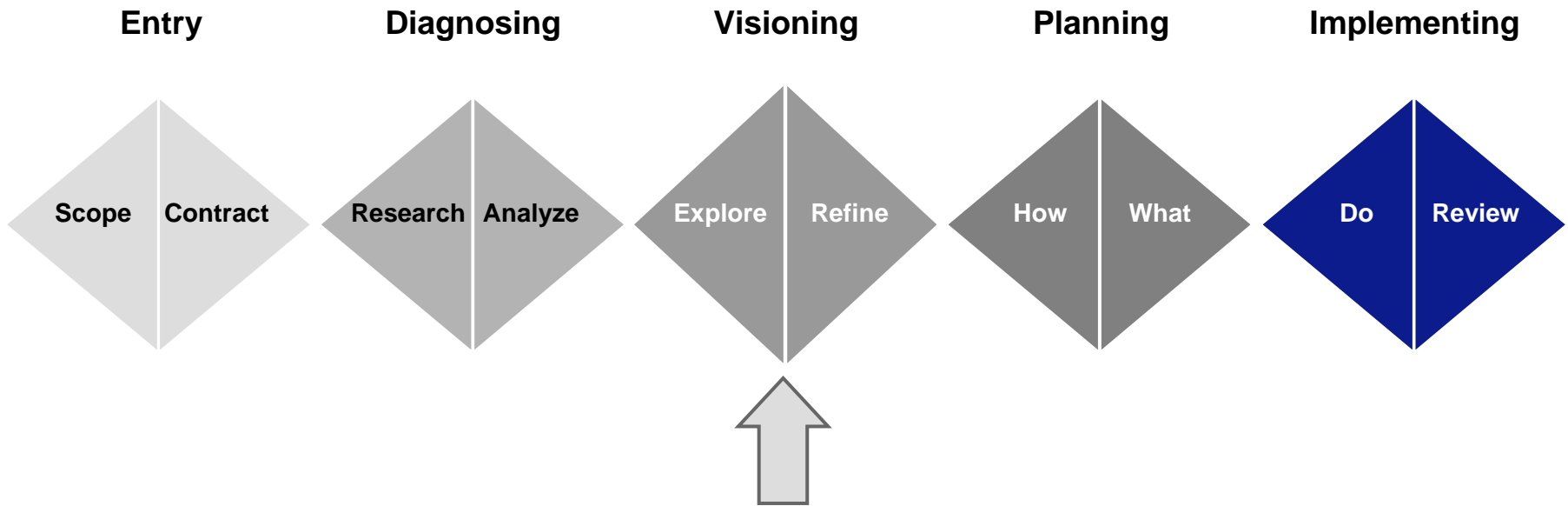
Date: March 13<sup>th</sup> 2008



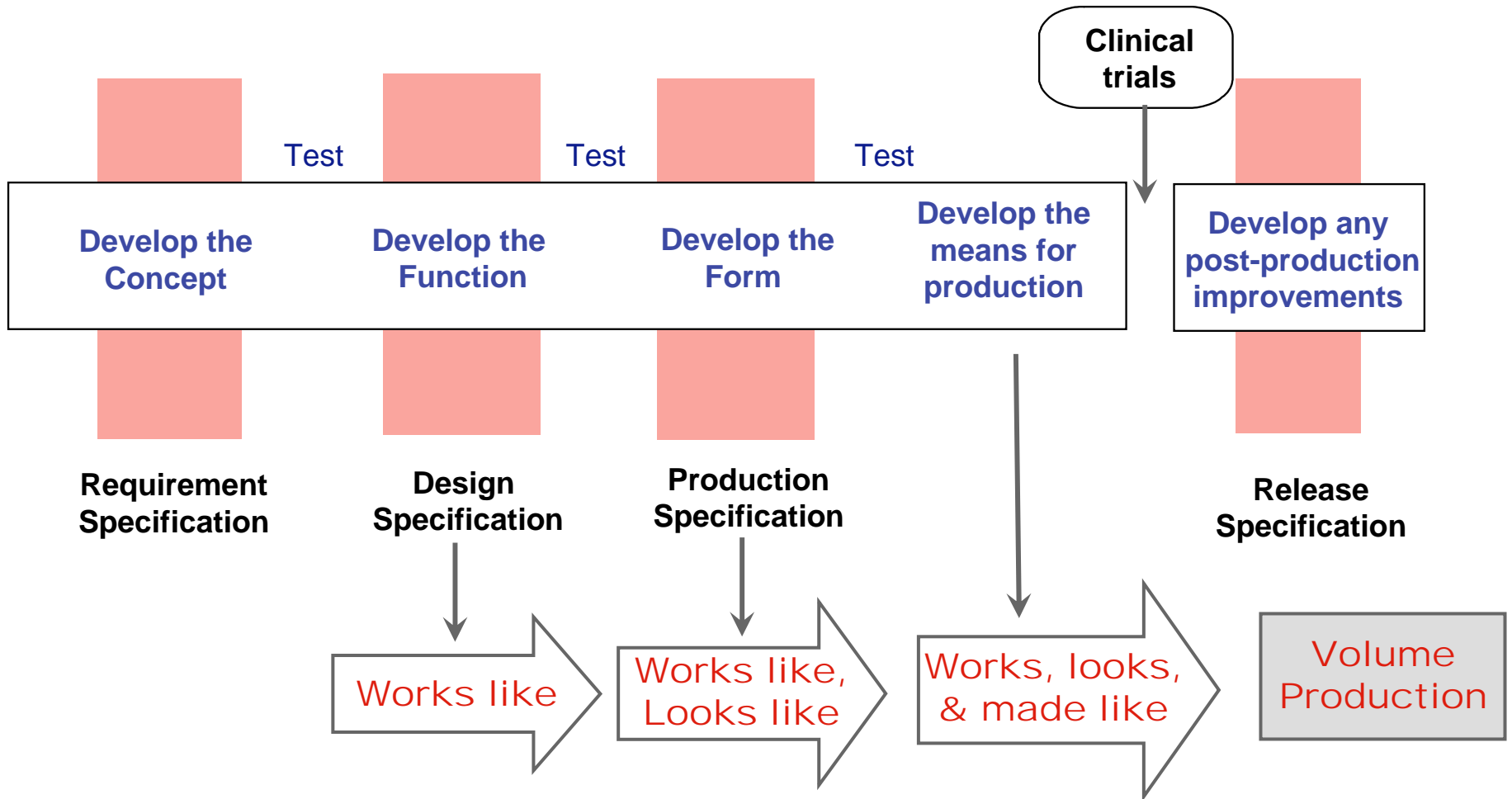
# PA's Role

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



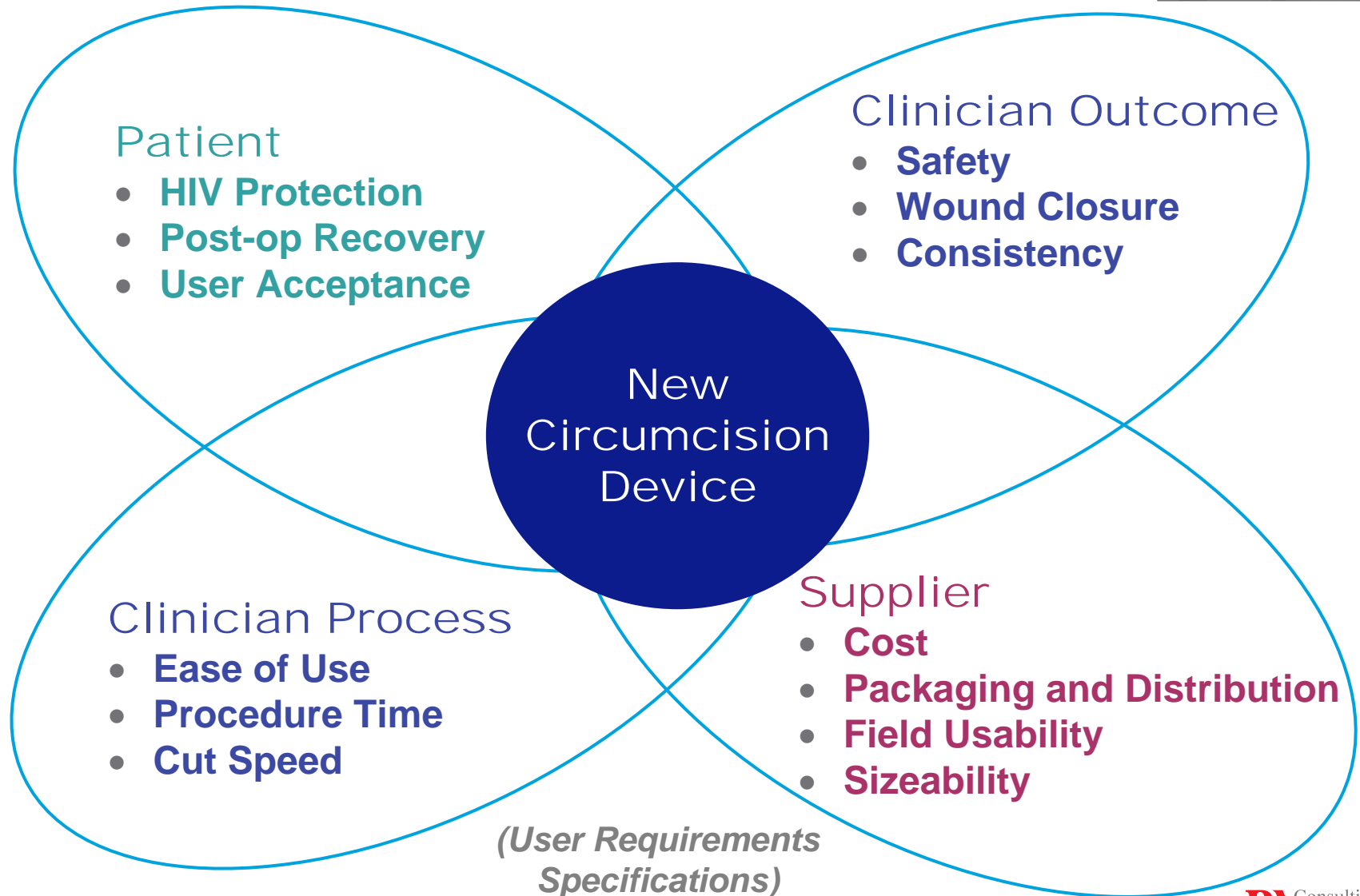
# Concept to Production



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



## Hitting the Right Target



# A Device Approach – The Steps Forward

## Today

**Save lives  
immediately**

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**Provide training,  
supplies, doctors,  
etc. for existing  
methods of Adult  
Male circumcisions**

## Tomorrow

**Introduce  
existing devices**

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**Evaluate various  
necrosing clamps  
currently on the  
market and select one  
or more to pilot in  
Africa.**

## The Future

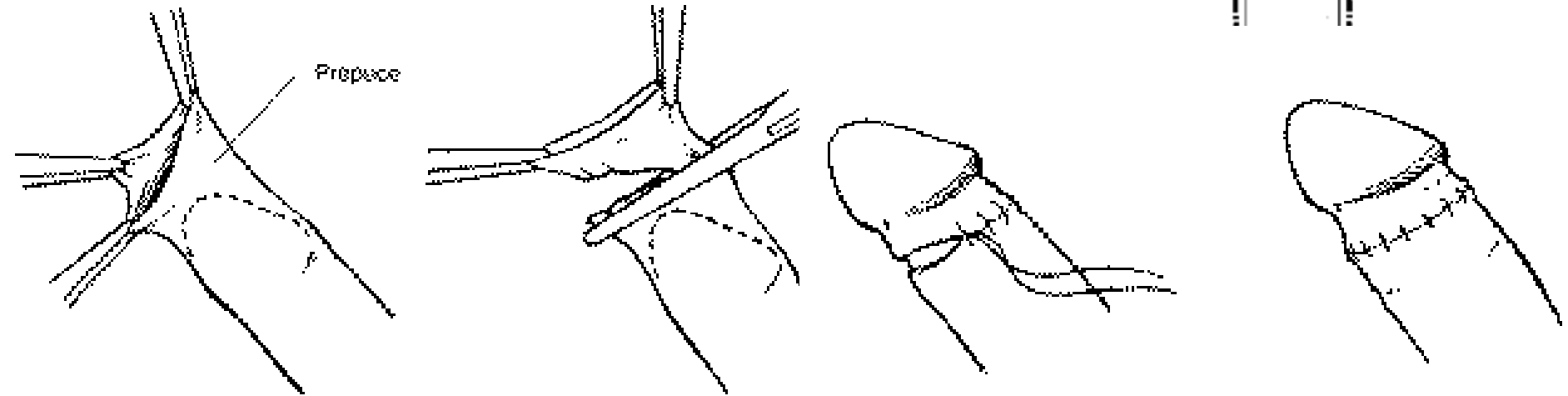
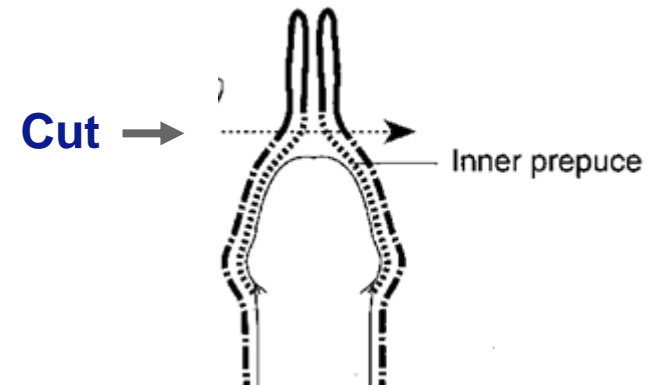
**Develop Ideal  
Approach**

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**Develop two  
concepts, one an  
advanced necrosing  
style clamp and  
second a temporary  
clamp with guided  
closure device.**

# Classification of Circumcision Clamping Devices

## Forceps Guided Method

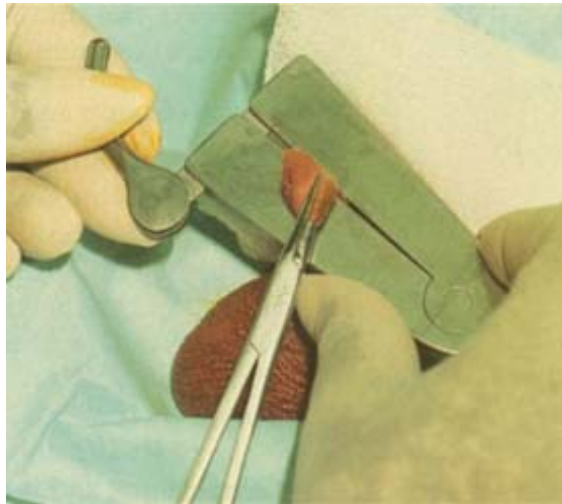
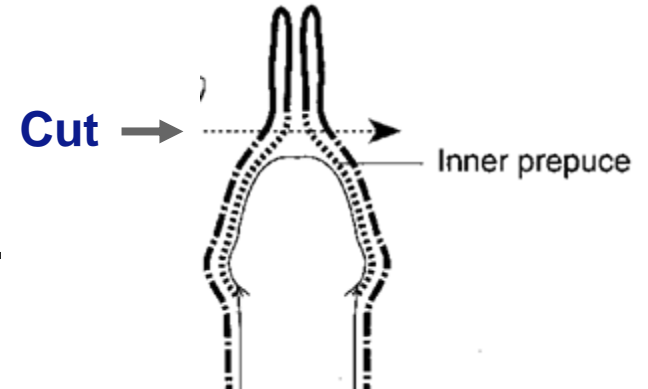


- **More stitches may be required than with other methods.**
- **Suturing step is time consuming**

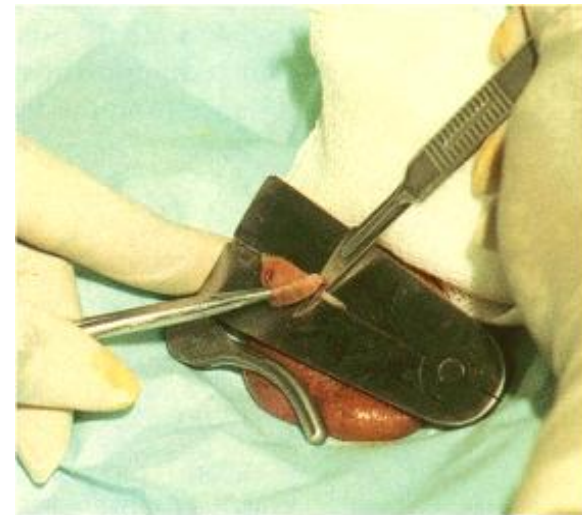
# Classification of Circumcision Clamping Devices

## 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

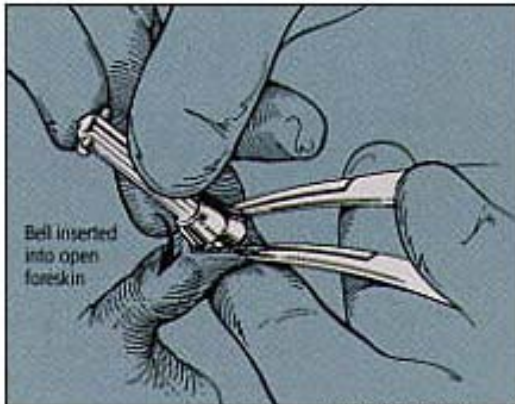
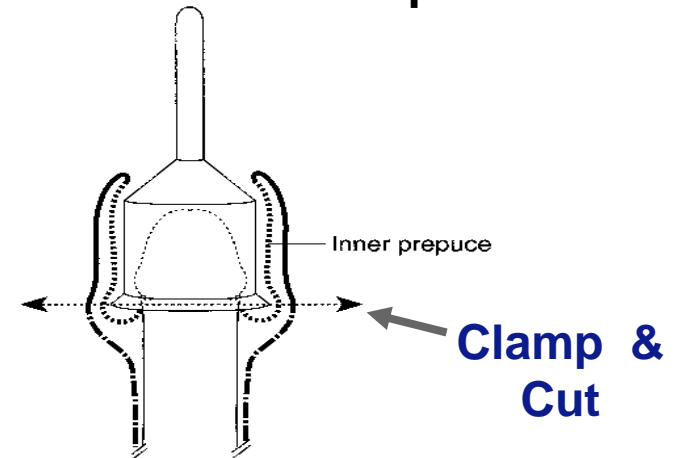


While the Mogen clamp remains closed, the prepuce is excised distal to the clamp.

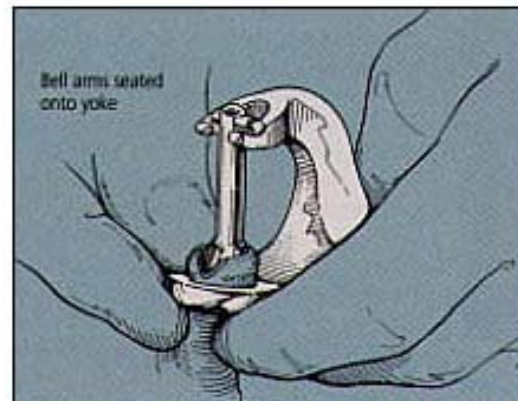
# Classification of Circumcision Clamping Devices

## Temporary Crush – Gomco Clamp

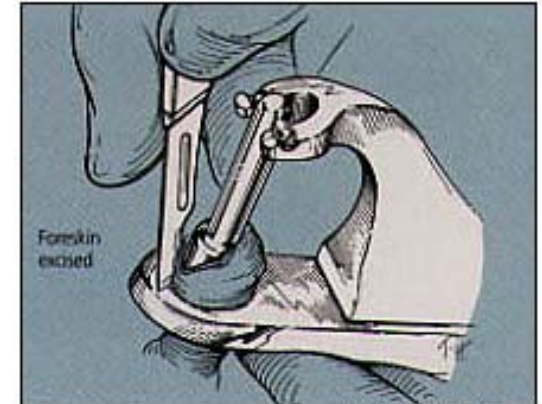
- The Gomco Clamp, by its very design, removes a larger portion of the inner foreskin than does the forceps guided or freehand techniques.
- For adults suturing is required



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# Classification of Circumcision Clamping Devices

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## Necrosing Device

### What is a Necrosing Device?

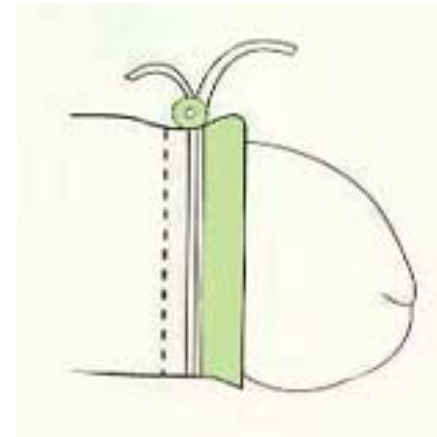
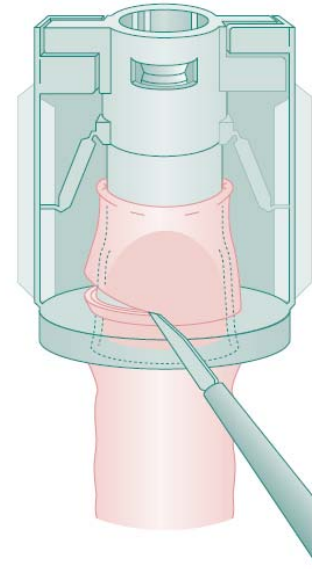
The foreskin is clamped or tied off, similar to umbilical cord removal.

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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?*

**Off The Shelf**

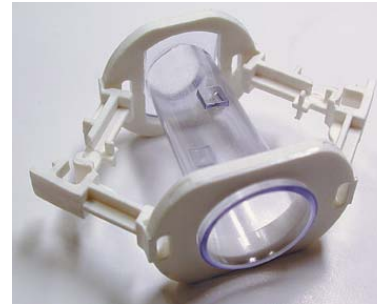
# Necrosing Clamps



Sunathrone  
Clamp



Tara Klamp



Smart Klamp



Ismail Clamp



Kirve Klamp



Plastibell



Zhenxi Circ  
Ring



ALI'SKLAMP®

## Introduce Existing Devices

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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.**

**Safer - Protects the glans during  
circumcision**

**Minimal to no bleeding**

**Easy to perform the operation**

**Disposable**

**Pre-sterilized**

**Avoids cross infections**

**A clean line of excision; helps  
to promote rapid healing**

**No special dressings required**

**No stitching required**

## Sounds Too Good

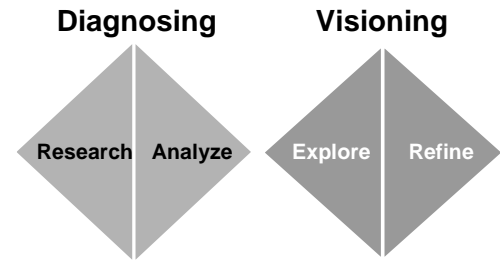
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What are some of the unknowns about Necrosing Clamps?

- 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.**

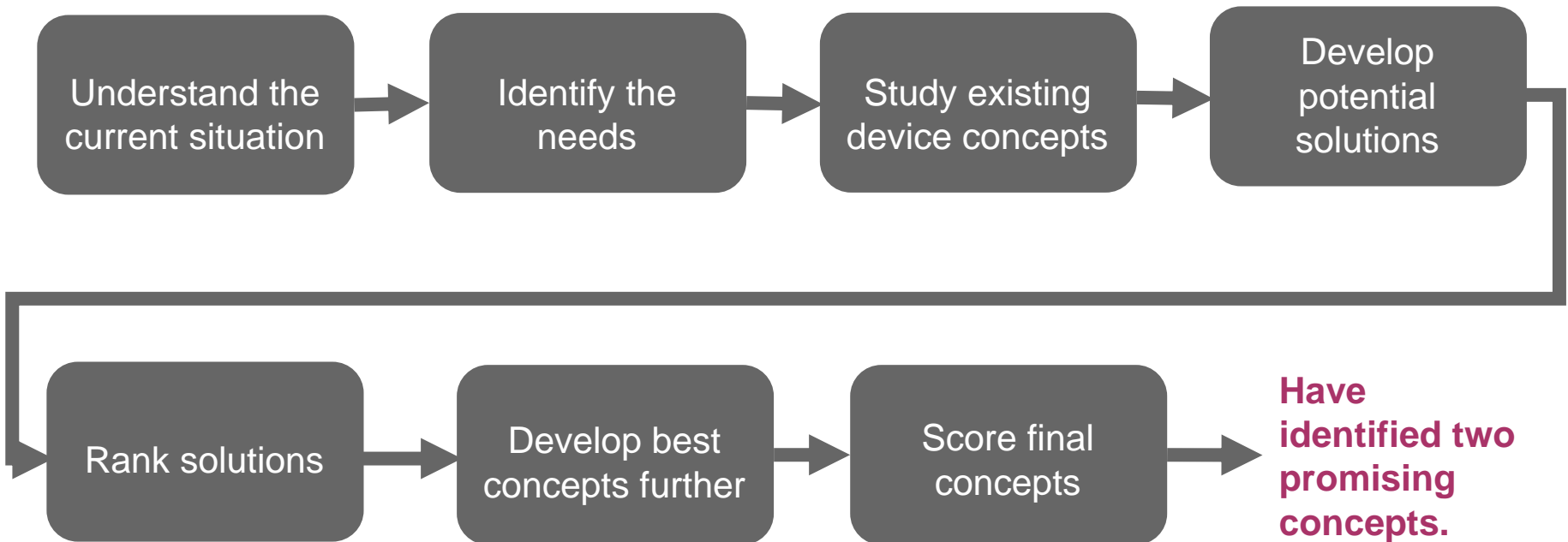
# Develop Ideal Approach



The Goal:

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

## The Concept Development Process



# 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	Process
<ul style="list-style-type: none"><li>• Safety</li><li>• Ease of Use</li><li>• Procedure Time</li></ul>	<ul style="list-style-type: none"><li>• Wound Closure</li><li>• Consistency</li><li>• Cut Speed</li></ul>

Advanced  
Necrosing  
Clamp

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

Clinician	
Outcome	Process
<ul style="list-style-type: none"><li>• <b>Safety</b></li><li>• <b>Ease of Use</b></li><li>• <b>Procedure Time</b></li></ul>	<ul style="list-style-type: none"><li>• <b>Wound Closure</b></li><li>• <b>Consistency</b></li><li>• <b>Cut Speed</b></li></ul>

Temporary Clamp  
with Guided  
Closure System

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**

### Advanced Necrosing Clamp

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

Pre-Sterilized – No sterilization required in the field.

Estimated Cost – \$15 - \$20.

Requires no electricity – no external power source required.

### Temporary Clamp with Guided Closure System

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.

# What are the things to be successful?

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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.)

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# 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**

Will any of the current models meet the current needs?

Off The Shelf

Necrosing Clamps

Sunathrone Clamp

Tara Klamp

Smart Klamp

Ismail Clamp

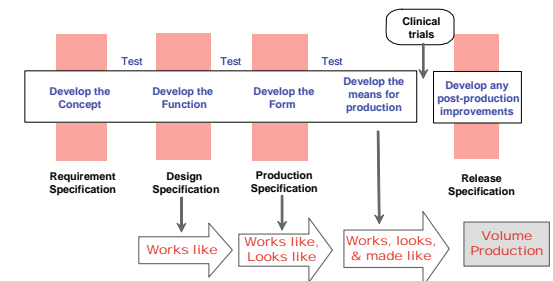
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