



# MOUTH PROP PROJECT

By the students :

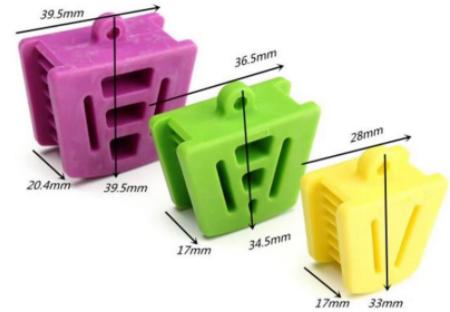
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# Introduction





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# 01-Design classification

Mouth prop is in Class I because it is:

2. Intended for transient use



1.Invasive devices(not surgically)

invasive devices with respect to  
body orifices

3.Not connection to an active  
medical device

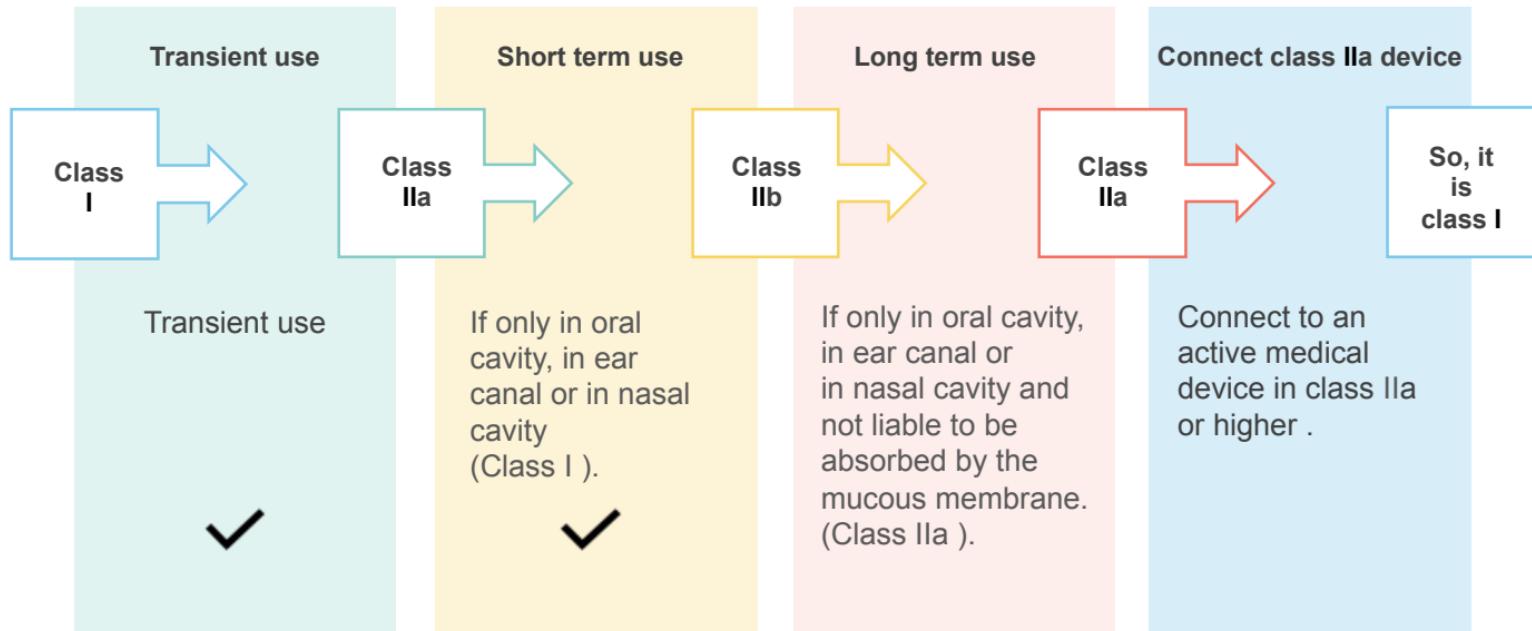
Not intended for connection to an  
active medical device ,Or are  
intended for connection to an active  
medical device in Class I

4.Intended for short time

Are in class IIa ,except if they are used in the oral cavity as  
far as the pharynx, in an ear canal up to the ear drum or in  
a nasal cavity in which case they are in Class I

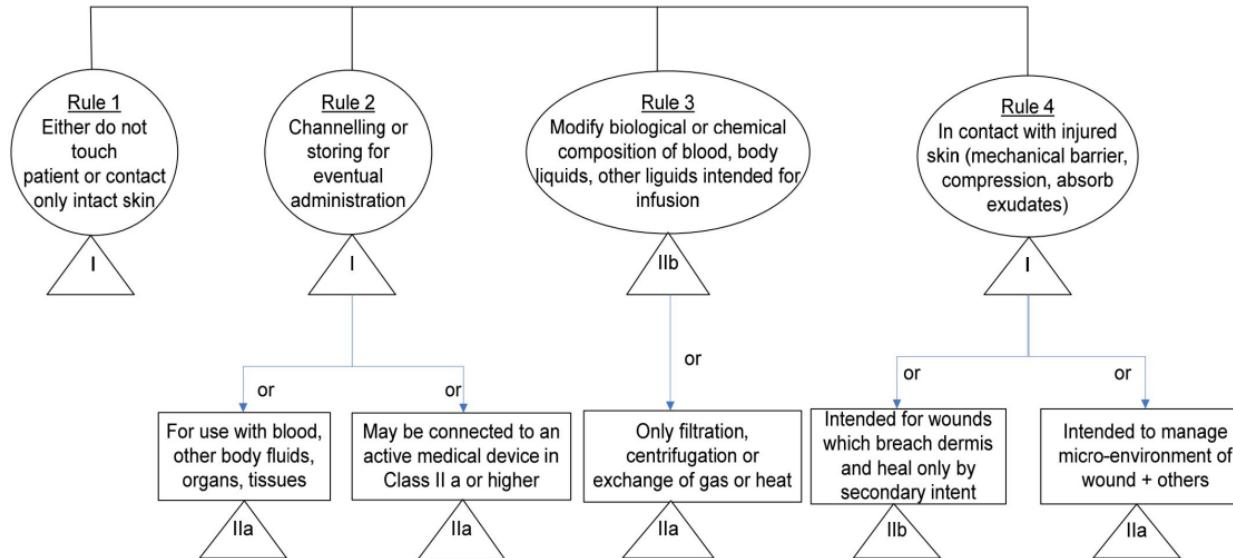
# 01-Design classification

**Rule 5: Invasive in body orifice or stoma (not surgically)**

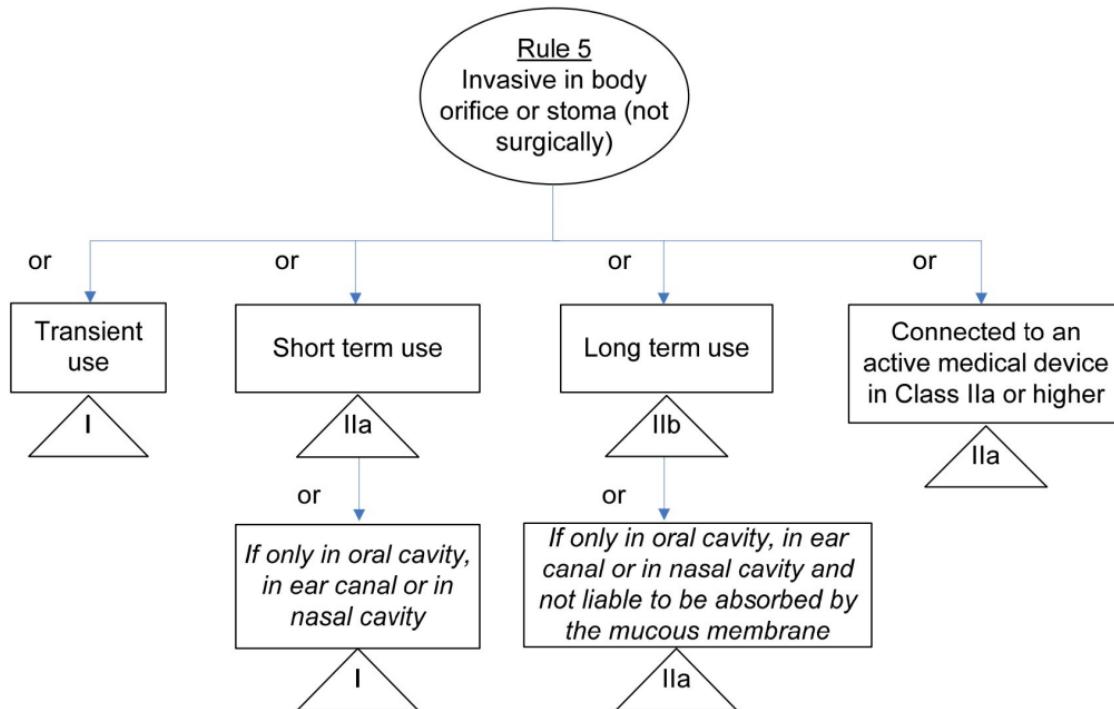


# 01-Design classification

## NON INVASIVE DEVICES

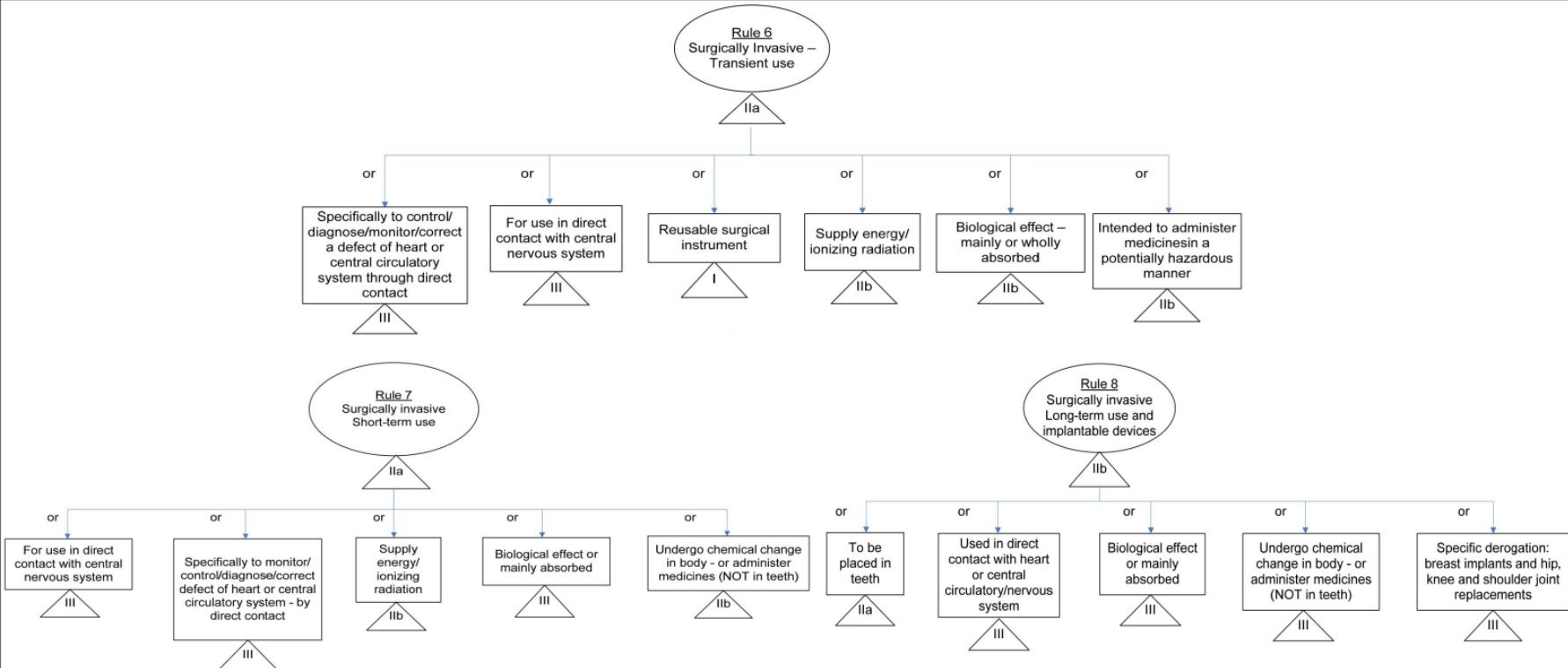


# 01-Design classification

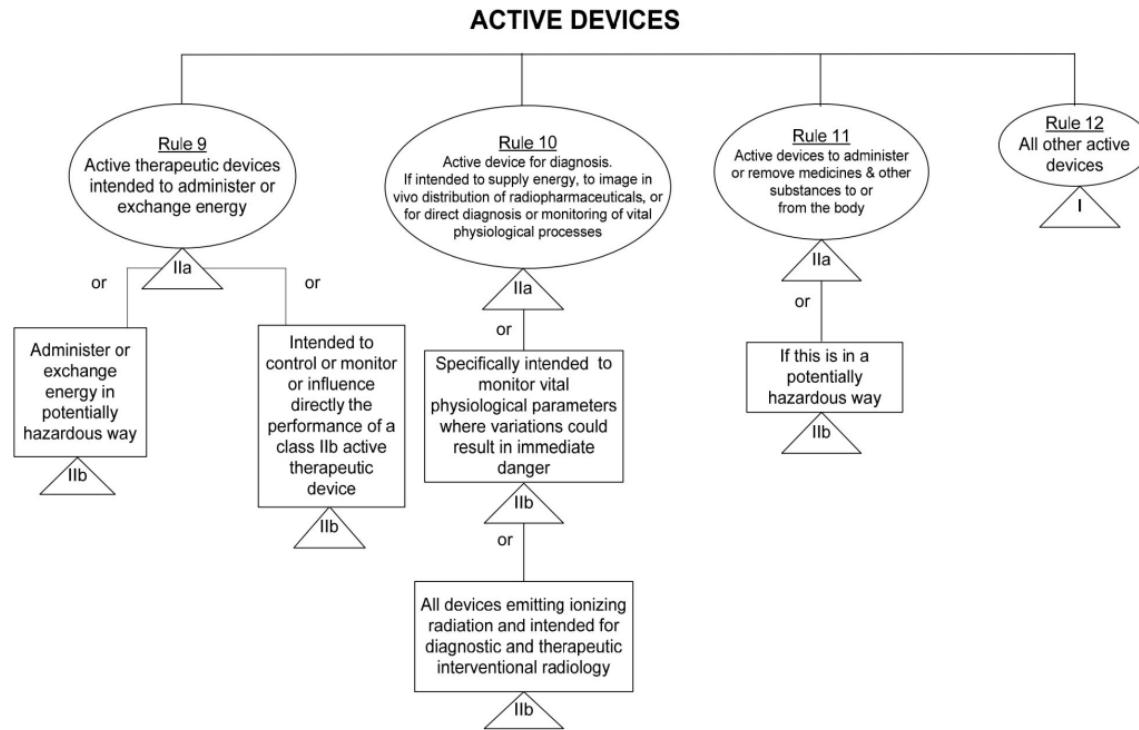


# INVASIVE DEVICES

## 01-Design classification



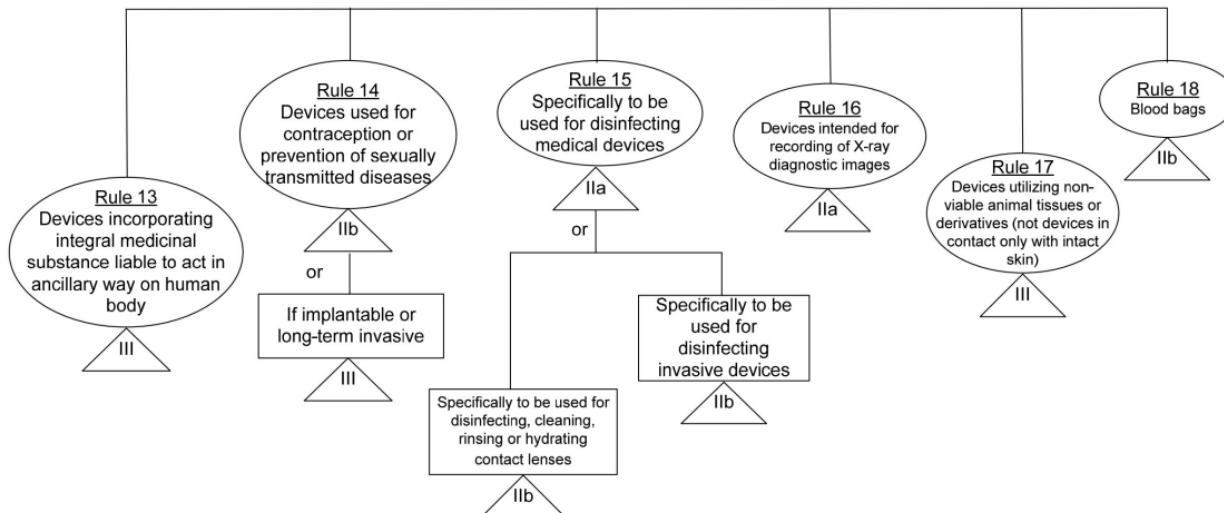
# 01-Design classification



# SPECIAL RULES

## 01-Design classification

### SPECIAL RULES



# 02-Product design specifications

## 1- Customer

### **Multiple sizes:**

The possibility of changing the size based on the size of the patient's mouth.

### **Stable:**

It does not move left or right, forward or backward.

## 2- Regulatory and statutory

### **European Union:**

European Commission (CE).



## 3- Technical

### **Product dimensions:**

Tool dimensions (35\*28 mm)  
Button size (3 rad )

### **Product materials:**

Inside used material (structure material): plastic.  
Outside used material (covered material): latex free rubber.

### **Opening degrees:**

Open range ( 0 degrees- 65 degrees).

## 4- Performance

### **Servicing:**

100 use, and sterilization after each use until recycling.

### **Weight:**

The maximum load is based on 98% person in the world =890 N.

### **Sterilization temperature:**

Using Dry-Heat sterilization at 180 degrees for half hour.

### **Melting point:**

600 degrees to melt the rubber and recycle it.

# 02-Product design specifications

## 5- Sales

### Selling price:

Not to exceed 60 SAR with a gain margin of 40%.

### Sales:

2000 per year.

### Color:

light blue is the most requested color.

## 6- Manufacturing

### Cleaning:

The Prop needs cleaning post-manufacture.

### Material used:

Composites (rubber + plastic), latex free.



## 7- Packaging and transportation

### Packaging form:

each prop packaged alone after sterilization.

### Transportation form:

A box containing 12 pieces.

## 8- Environmental

### External packaging:

Recyclable.

### Internal packaging:

We can Recycle both the rubber and plastic.

### Servicing:

Reusable.

# 03-Detailed design

## The CAD model

We designed the MOUTH PROP by using the professional 3D CAD software (fusion360)

### 1. Mouth prop

Consists of :

- Button
- Hole
- Sinuous surface

### 3. Hole

Hole used for fixing tongue guards tool .

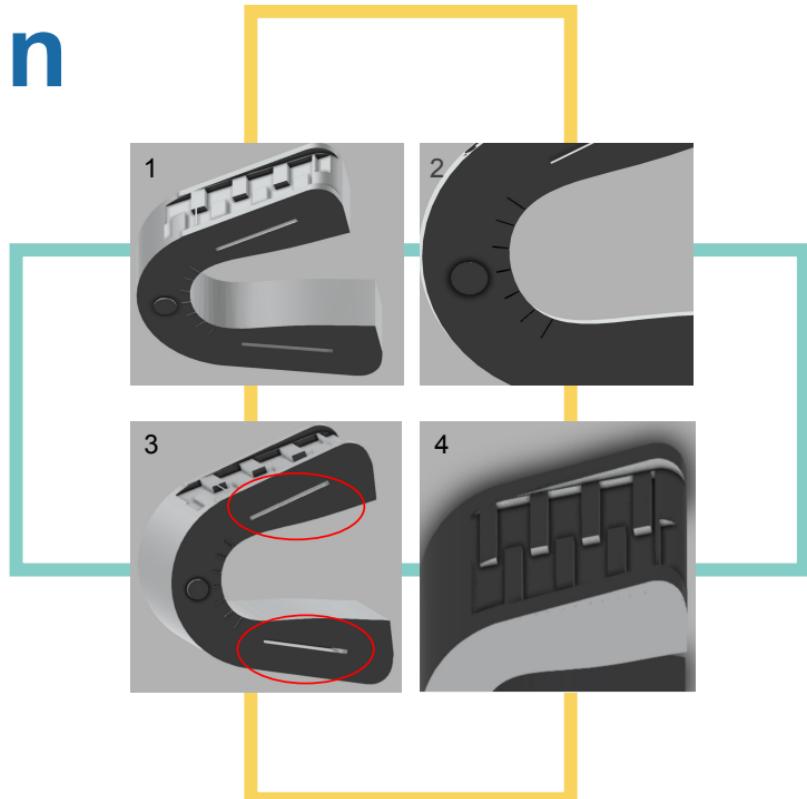


### 2. Button

A button to change the size , with more than one angle.

### 4. Sinuous surface

Surface in line with the teeth.



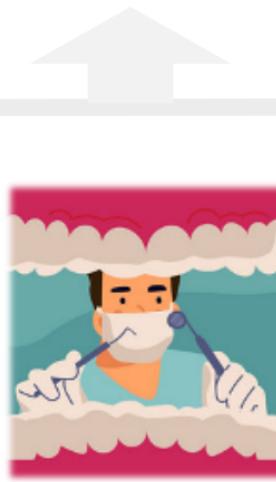
The design model link: <https://a360.co/31ZNLDh>

# 04-Design evaluation and Risk assessment



## Verification

- Effective safety(latex free, no metals) device.
- Comfortable.
- Maintain mouth opening.
- Non slip tooth channels.
- Can be set to multiple size.
- With Tongue Guards.



## Validation

- It moves out of its position due to insufficient dimensions of the upper and lower parts that hold it in its position.
- The piece of plastic that defines the size breaks down due to the force of pressure.
- Sizes are inaccurate and insufficient.

# Risk Assessment

## Risk 1

The piece of plastic that defines the size breaks down

**Why is it breaks down?**  
It breaks down due to the force of pressure.

**How can we reduce the possibility of failure (breaks down)?**

By change the type of plastic grades, will improve its hardness.



## Risk 2

Rubber collapses and flattens

**Why the rubber collapses and flattens?**  
It collapses and flattens due the influence of frequent and strong bites.

**What is the main cause of rubber collapses and flattens ?**

Insufficient stiffness

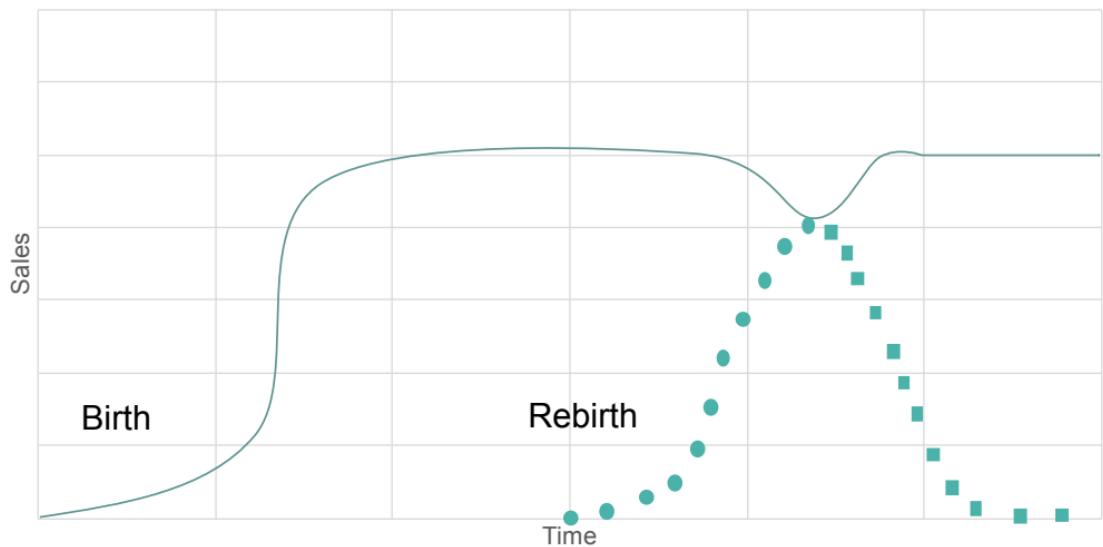
**How can we improve its stiffness?**

Either by adding powder to increase the stiffness or reduce the amount of rubber oil equivalent to reduce the softening effect of rubber product, played a role in improving the stiffness.

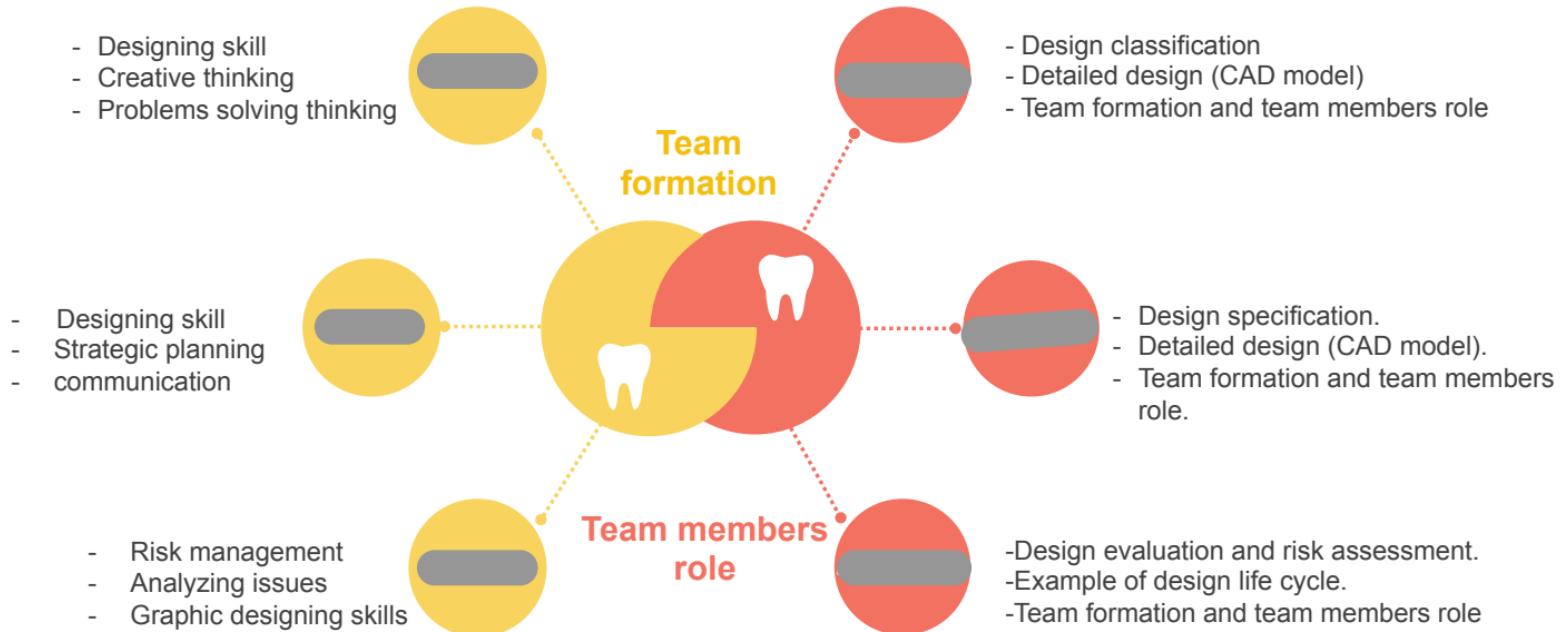
# 05-Example of design life cycle

## Mouth prop rebirth:

Adding an additional feature such as Holder for saliva ejector tube (suction).



# 06-Team formation and team members role



# Thank you

Do you have any questions?

