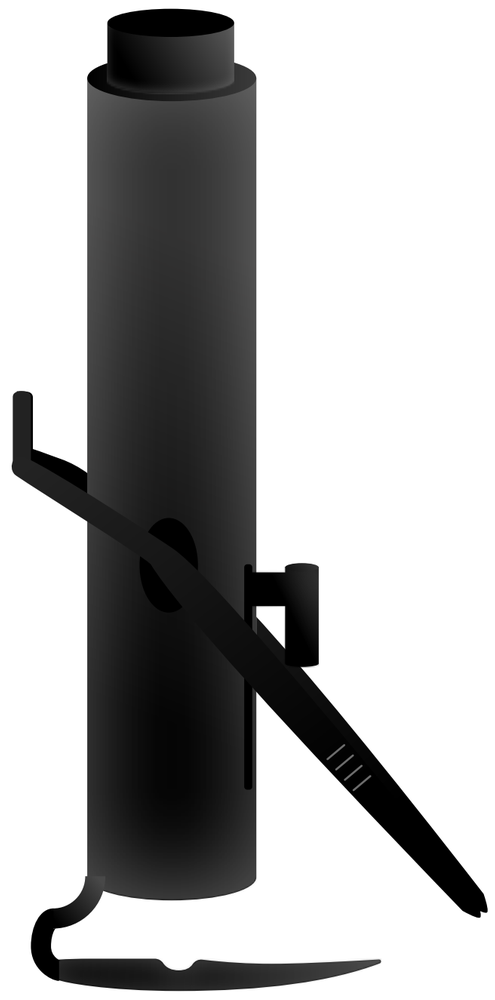

Dissuo

a user-friendly medical device

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Problem

Problem Overview

Current suture removal processes lead to inefficiency for physicians as they incur opportunity costs due to post-operative care obligations. Lack of transparency leads patients to unnecessarily spend extra money at pharmacies like CVS or to opt for self-removal.

Scissors and tweezers might be safe for doctors, but they are potentially dangerous and awkward in an untrained hand.

A device that saves doctor's time and facilitates easy, safe removal resolves these issues.

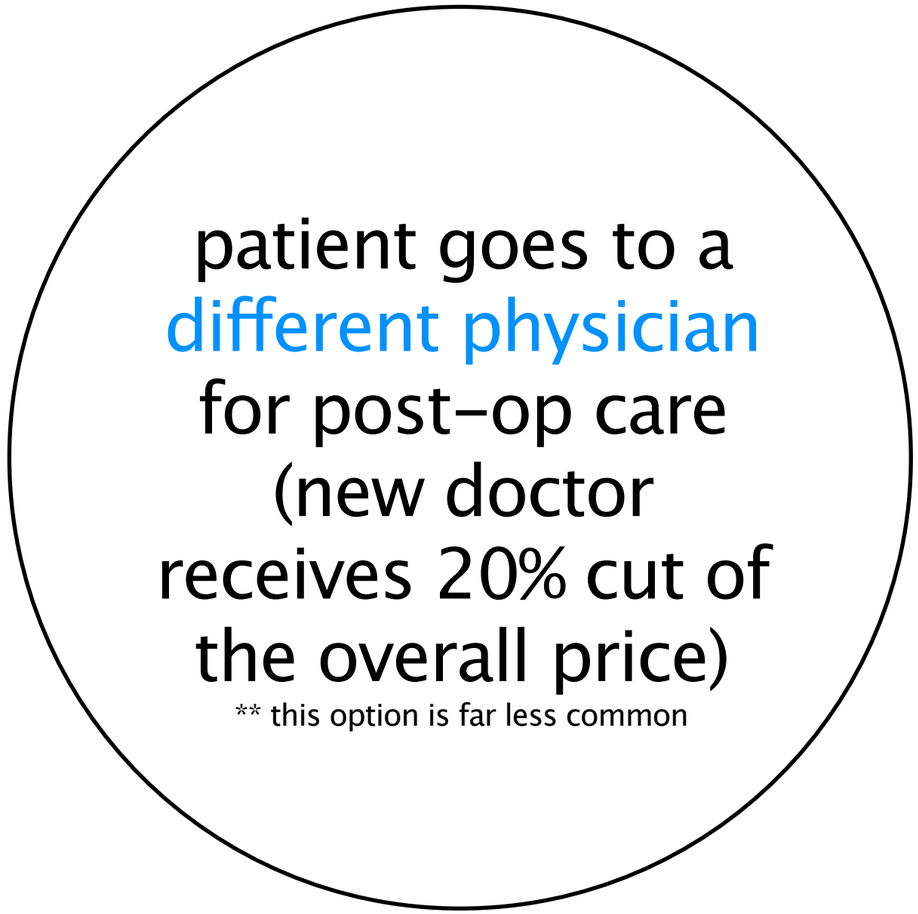
Cost of Suture Removal

lack of transparency +
unnecessary costs

Breakdown

cost of suture removal is bundled with price of original surgery – not returning for post-op does not negate charges for post-operative care

Option 1



Option 2

**These costs cannot be negated by our device

Physician Opportunity Costs

exist because of post-operative care

→ global period

usually 10-14 days for a minor wound - contractually prevents any future billing by physicians (for that medical issue)

=

opportunity costs ←

paying overhead, staff, and can't see paying patients

Our device would minimize opportunity costs incurred by physicians by facilitating the removal process or limiting a post-op checkup to wound inspection, with removal responsibility transferred to a capable patient.

Unnecessary Costs

incurred by patients

seek removal outside doctor office

Patients often choose to go to CVS, Walgreens, or similar locations to get sutures removed, which adds avoidable costs as a result of lack of transparency (they still paid for post-operative care in full)

CVS Minute Clinic charges $99-$139 for suture removal on a minor wound

Our device would be a one-time purchase for a smaller fee, thus allowing for safe removal while preventing patients from falling into these pricing traps.

Current Method

Process

1. sterilize utensils
2. wash location of stitches
3. gently pull each knot
4. slip scissors in loop
5. cut the stitch
6. pull suture out
7. clean wound
8. apply adhesive strips
9. apply ointment

Safety Concerns

self-removal is

difficult and dangerous

* and on certain parts of the body physically impossible

Medical News Today writes on how self-removal is difficult and dangerous with many pitfalls for the untrained hand. Wielding two instruments simultaneously greatly increases the risk of stabbing or aggravating the wound

Research

User Data

110 million

people go to the emergency room per year

~12 million

patients get treatment on a minor laceration annually

2 per year

amount of sutures for an average person in Britain

~70%

of people we surveyed have had sutures

Why Stitches?

use if…

- cut is deep enough to expose the dermis
- blood flow doesn’t stop after applied pressure
- edges of the wound need to be pushed together

Reparation Process

- keep wound bandaged and dry for 48 hours
- remove bandages and clean daily
- after removal

  scar massage
  moisturize
  protect from sun
  no daily activity

Post-Treatment Consequences

infection rate of lacerations treated in ED

While a 5% infection rate is low, the issue needs to be addressed by our product as patients take on post-operative care responsibility when they opt for self-removal.

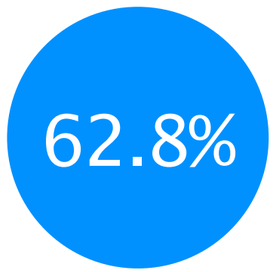
Opportunity

NIH Study

Of those given instructions on how to remove stitches at home…

chose to complete the task themselves

Of those not given instructions on how to remove stitches at home…



still chose to remove sutures at home

Patients express a willingness and tendency to remove their own sutures, making it necessary that they have a product that is safe, convenient, and minimizes extra cost.

Aversion to Doctors

The general public will not regularly visit their primary care physician for these reasons

44% don't regularly visit their primary care physician for financial reasons

27% don't want to take time off from work

21% prefer natural remedies

12% would rather diagnose themselves using sites like WebMD

People's aversion to the doctor's office increases the likelihood that they purchase a product for self-removal

Online Forums and Websites

Top 3 YouTube videos on "Home Suture Removal" have a collective 2 million views

A city-data.com user left a comment in favor of self-removal on a query regarding suture removal options. His response amassed over 11.5 million views

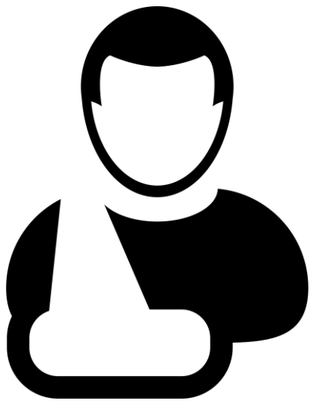
Wikihow has a page dedicated to guiding users through home removal

a simple google search on “how to remove stitches at home” yields detailed instructions to guide one through the process from sites such as Healthline, MedicalNewsToday, and MumsNet among many others

**Users of these sites express desire to remove their own sutures

Target Stakeholders: Patients

Dissuo is a safer and more convenient option for patients because



it saves patients from going to the doctor

patients can utilize the device in the comfort of their own homes

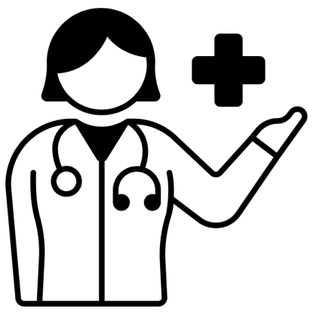
it is affordable

it protects the patient from further injury during the removal of stitches

it is easier than using scissors and tweezers for the untrained hand

Target Stakeholders: Doctors

Dissuo is a quicker and easier option for doctors because



it minimizes opportunity costs associated with post-operative care either by shortening post-op checkup or allowing them to give the device to the patient with instructions

Competitors

there is a lack of competing products that fills the whitespace, but these are some of the patents

FIG. 1A
(PRIOR ART)

Fig. 12

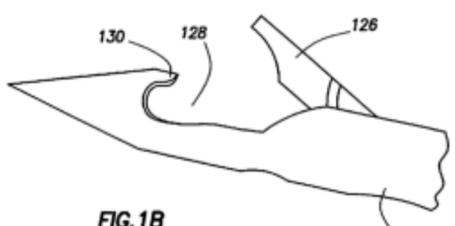


FIG. 1B
(PRIOR ART)

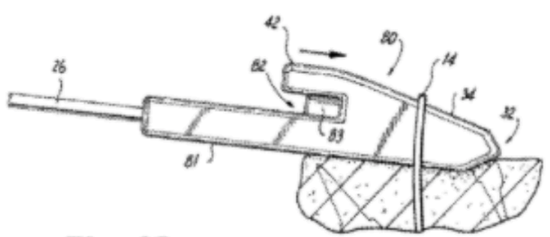


Fig. 13

the main competitor is scissors + tweezers

Issues with Current Patents

Safety The function of these respective designs require that the user apply force on their sutures in order to cut them. This is an extremely unsafe mechanism

User Friendliness No natural grip

Effectiveness Faulty mechanism

none of the aforementioned patents have made it to market for the reasons stated above so – none are truly competitive at this point

Alternative Methods

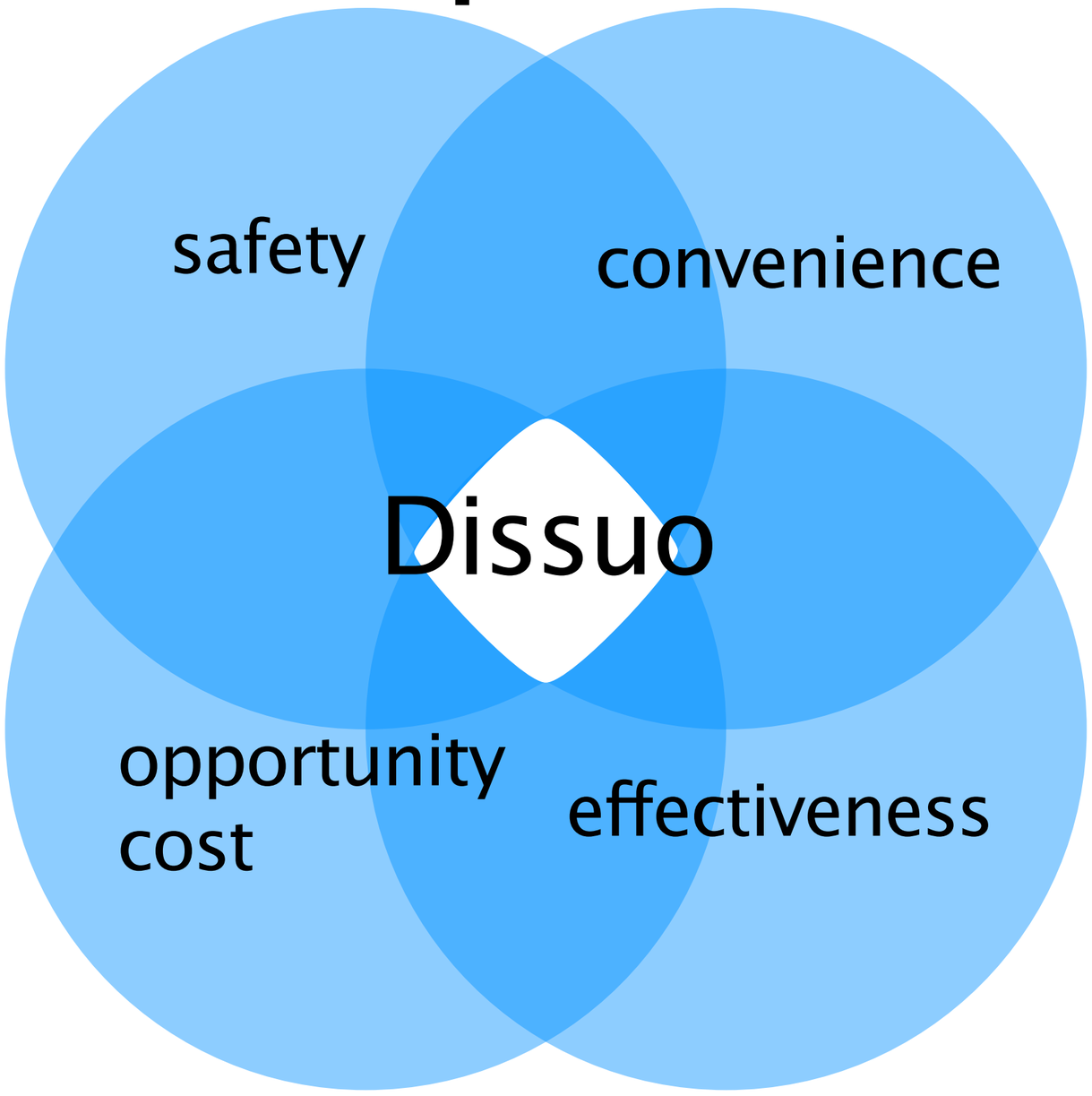
Patient's Perspective

	Safety	Convenience	Effectiveness	Opportunity Cost
Dissuo				
Doctor				
Current Home Removal				

Doctor's Perspective

	Safety	Convenience	Effectiveness	Opportunity Cost
Dissuo				
Scissors and Tweezer				

Whitespace



No suture removal device enables safe, convenient removal at home by the patient. While devices with a similar purpose exist, no product has successfully combined scissors and tweezers into a single device for use by a medical professional (while saving them time and money)

Solution

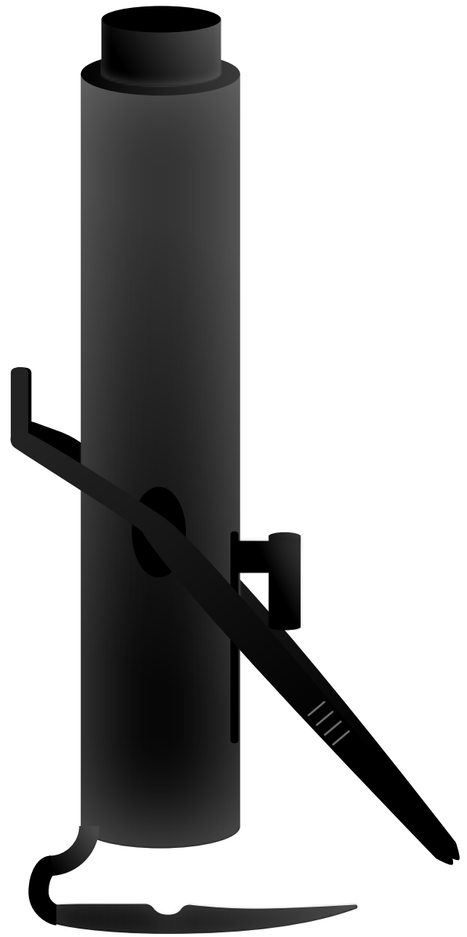
Product Requirements

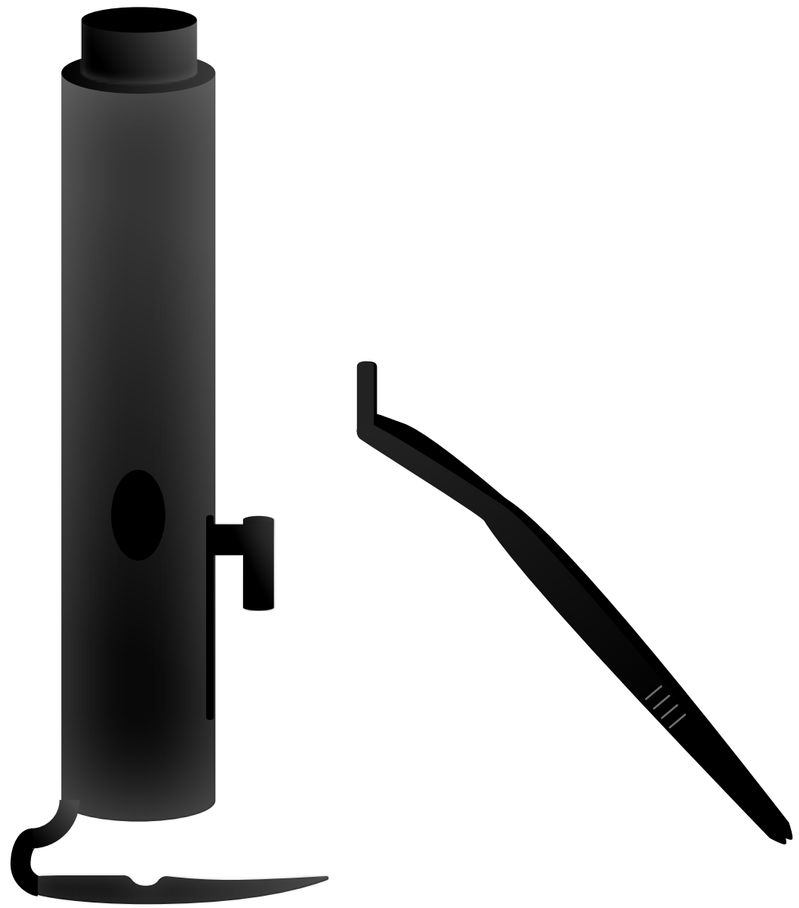
Needs	Requirements
safe	The scythe that slides under the stitch must adequately protect the user's wound from the blade The scythe must not be abrasive to the wound when it is used to slide under the stitch The scythe must adequately stop the blade
convenient	The device must be small enough to store easily in the household The mechanism must perform the task quickly
affordable	Device must cost no more than $20, making it affordable for almost anyone who wishes to use it

Product Requirements (cont.)

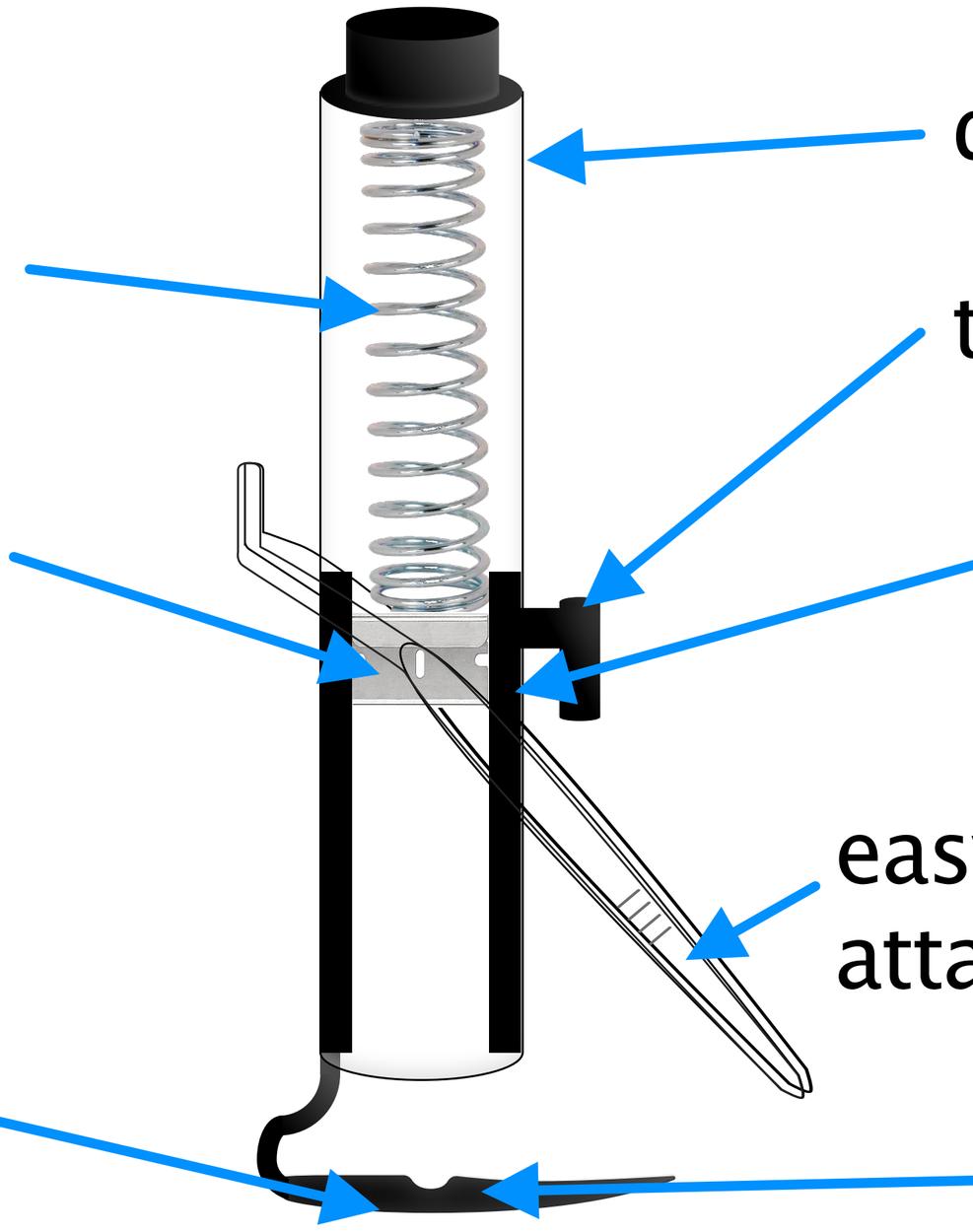
Needs	Requirements
quick and easy to use	The instructions on proper use must be easy to understand Handling the device must be easy to maneuver with one or two hands (some parts of the body require removal with one hand)
durable	The shell of the device and all its parts must last for at least 10 years Spring Blade Tweezers
aesthetic	The device must look pleasing to the eye

Design





Features



spring loaded mechanism

durable shell

trigger

steel-cut blade

guides for blade

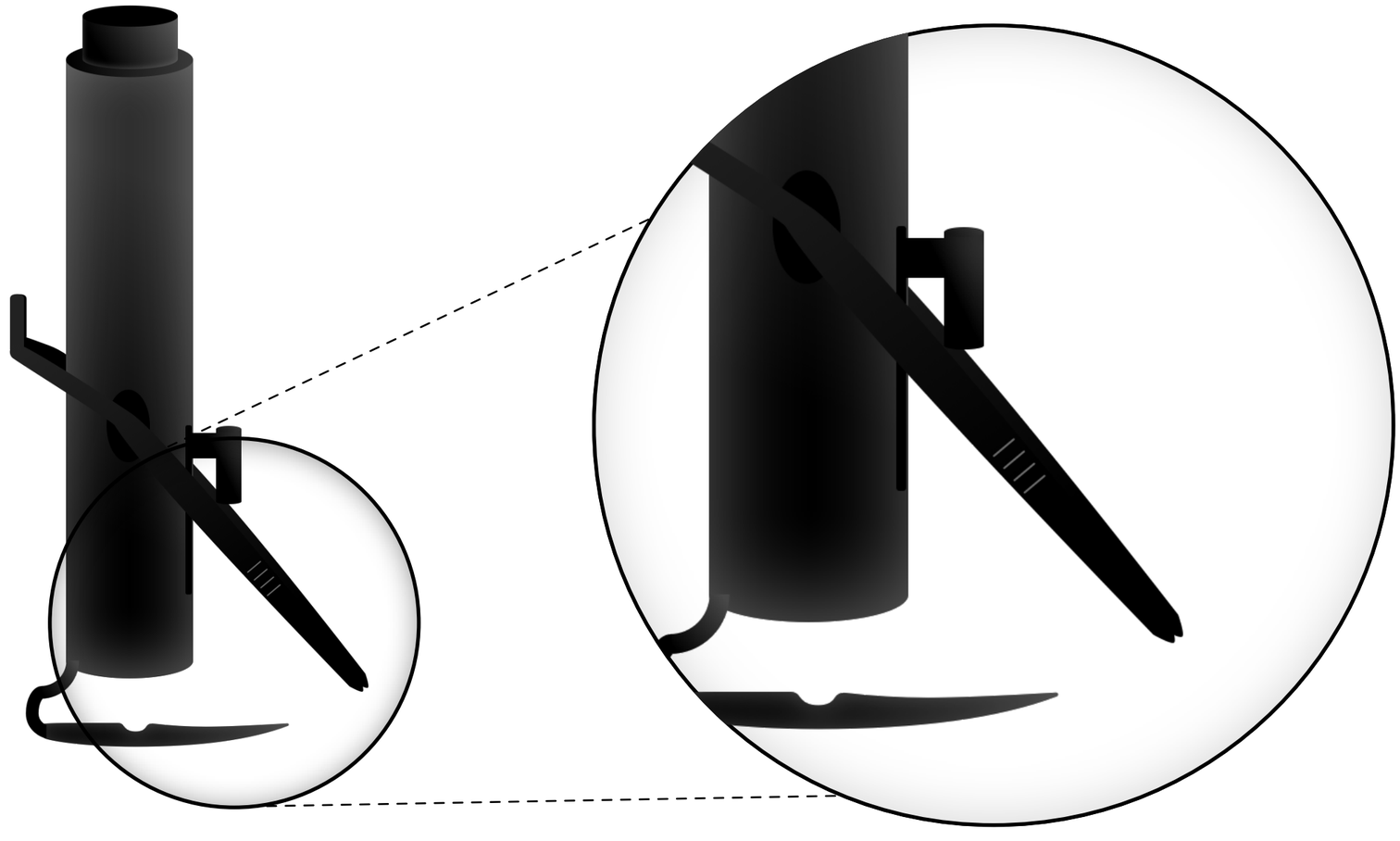
easy-use, removable attachment tweezers

anti-abrasive padding under scythe

scythe

Mechanism – Step 1

Use tweezers to uplift the first stitch by the knot**



** tweezers are a removable attachment, allowing doctors the freedom to use the device and the tweezers separately

Mechanism – Step 2

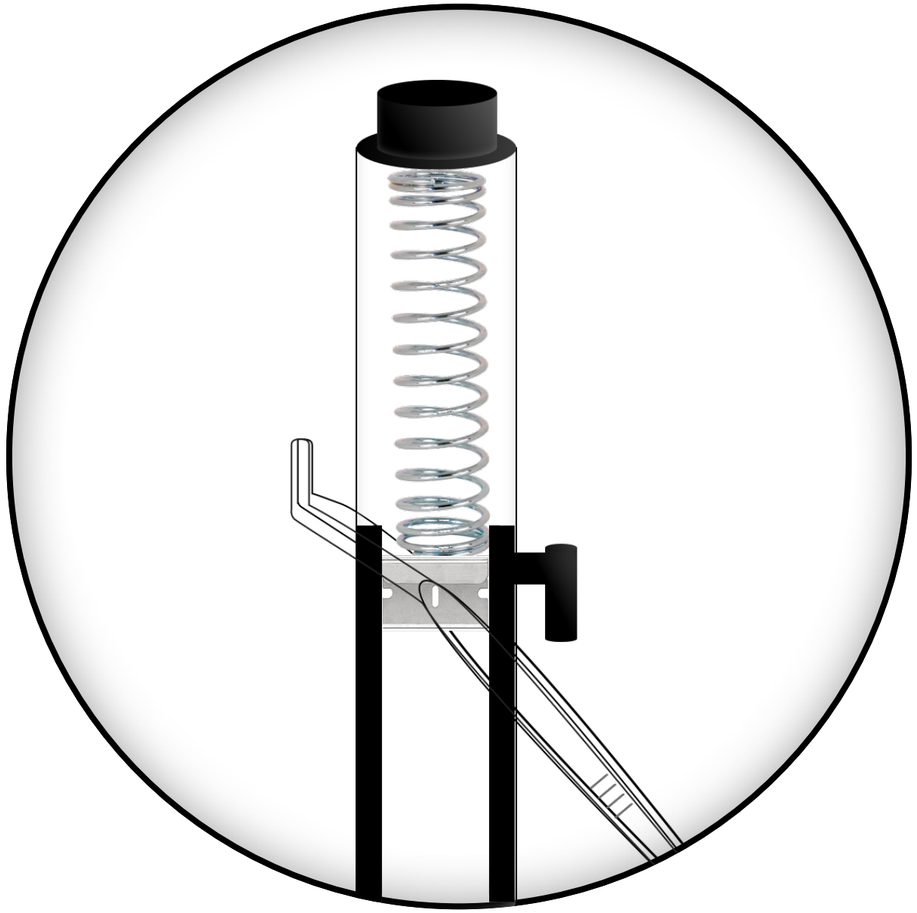
Rotate the device (in a pendulum fashion, not in a twist) and slide the scythe underneath the uplifted stitch

Mechanism – Step 3

Move the device further until the stitch falls into divot

Mechanism – Step 4

Press the trigger, allowing the spring loaded blade to chop the stitch



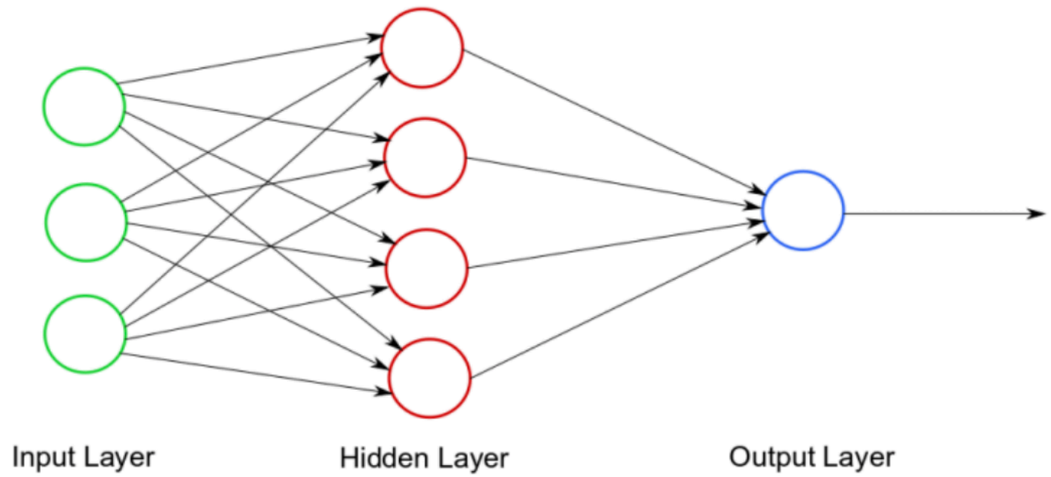
Mechanism – Step 5 after the blade cuts the stitch

Remove the device from the proximity of the wound
Use the tweezers to pull out the stitch
Cock the blade back into place by pushing the trigger on the front of the device upwards
Repeat the steps on the next stitch

Accessory App

To tell users when their stitches are ready for removal:

1. Take a picture of your wound
2. An AI recognition algorithm will analyze the picture
3. The app will classify this picture into two categories:
   3a. Infected
   3b. Not infected
4. If infection is present, consult a doctor
5. If not proceed with suture removal



An accessory app would add to the safety of opting for self-removal by removing risks surrounding rare cases of infection

Validation

Current Perception of Our Idea

* from the patient

data from 76 responders

~70% given an adequate device, they'd be comfortable with self-removal

~57% would spend up to 30$ dollars on a self suture removal tool

~85% would spend up to 20$ dollars on a self suture removal tool

An overwhelming majority of our college-age respondents would be comfortable with self-removal but do not have a high budget, which suggests a market for our product

Current Perception of Our Idea

* from the doctor

data from 9 medical professionals**

radiologists, urologists, physicians, and nurse practitioners answered the survey

> “Intuitive”
>
> “Great Design”
>
> “really cool, worry about suture knots and being "stuck" in the skin”
>
> “Favorable”
>
> “Interesting concept, nice to have scissors and tweezers in one device”

**number is limited due to current national circumstances

Current Perception of Our Idea

* from the doctor

quotes from the medical professionals

“Easy; does the knot have to be on a specific side; I can envision it being used with one hand at home by the correct patient.”

“Great idea, especially for home surgical suture removal…. I would suggest using the same language in the design and features images as the mechanism images. The only issue, is whether or not the tweezers are removable, since it is sometimes hard to keep the suture up, without holding it up to get the scythe under it.”

The doctors’ opinions proved to be very helpful. Almost all of them had only positive things to say about the idea and design, but a few of them did have questions and advice. The advice above about making the tweezers removable contributed to a change in our design (this feature was already being considered)

User Process

User 1:

Julia, 19, student at Northwestern

1. I slip and fall on ice on my way to class
2. I need stitches
3. The wound heals, but writing and typing is uncomfortable
4. I have two midterms, an essay, a lab report, and two job applications due in the next ten days
5. The health center has no appointments available in my schedule
6. I walk 10 minutes to CVS and purchase this product
7. It cost me the equivalent of a meal at a restaurant, but I can remove my stitches and get back to my activities normally

User 2:

Steve, 35, residency student from Boston

1. I am working at a children's hospital in Boston, where I often stitch wounds- and eventually remove sutures.

2. I am comfortable with the procedure and can do it at a very high level, but when there are a lot of stitches, scissors and tweezers are tedious.

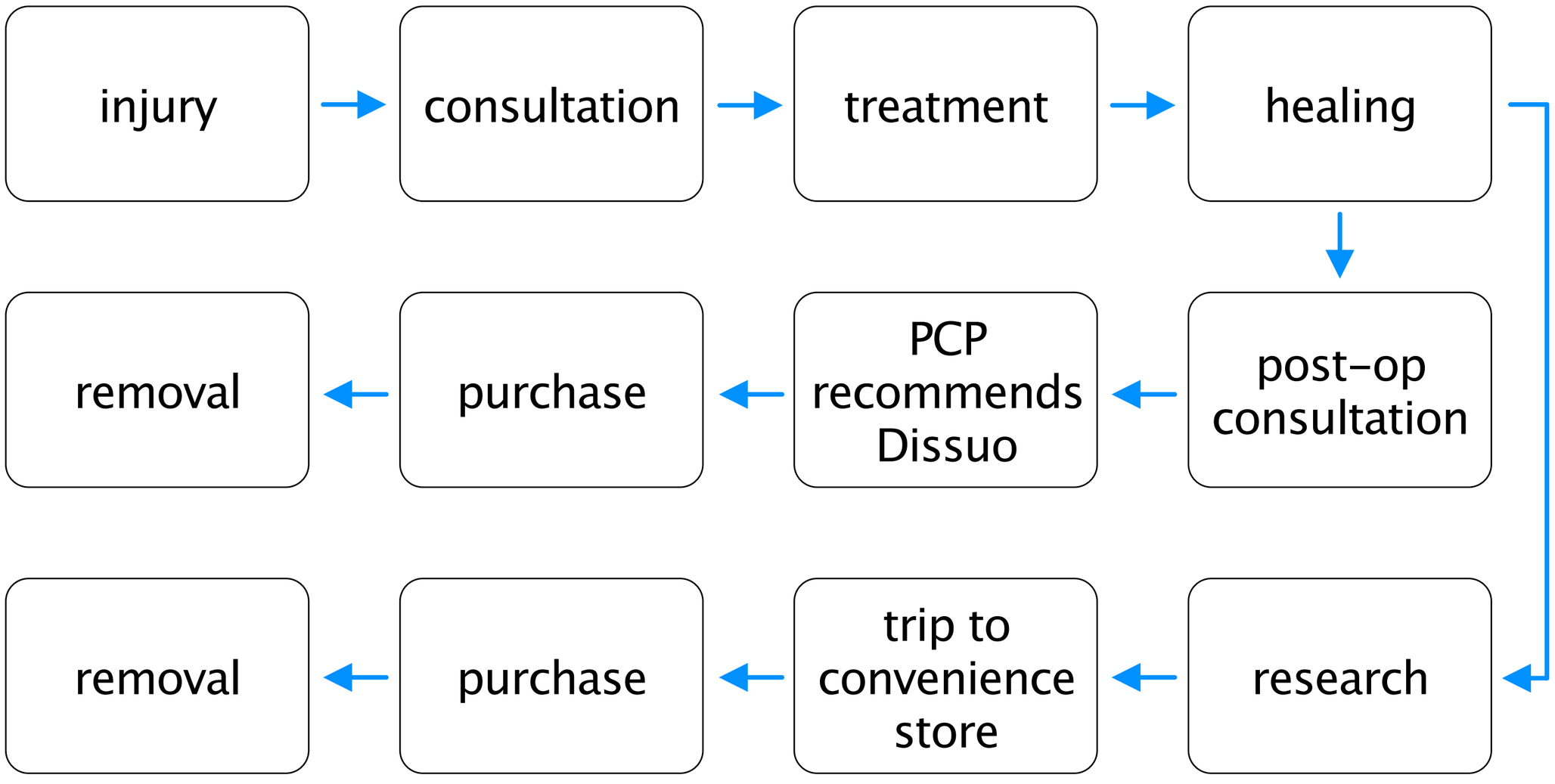
3. When I use Dissuo, I can save a little bit of time and the removal process feels safer.

User 3:

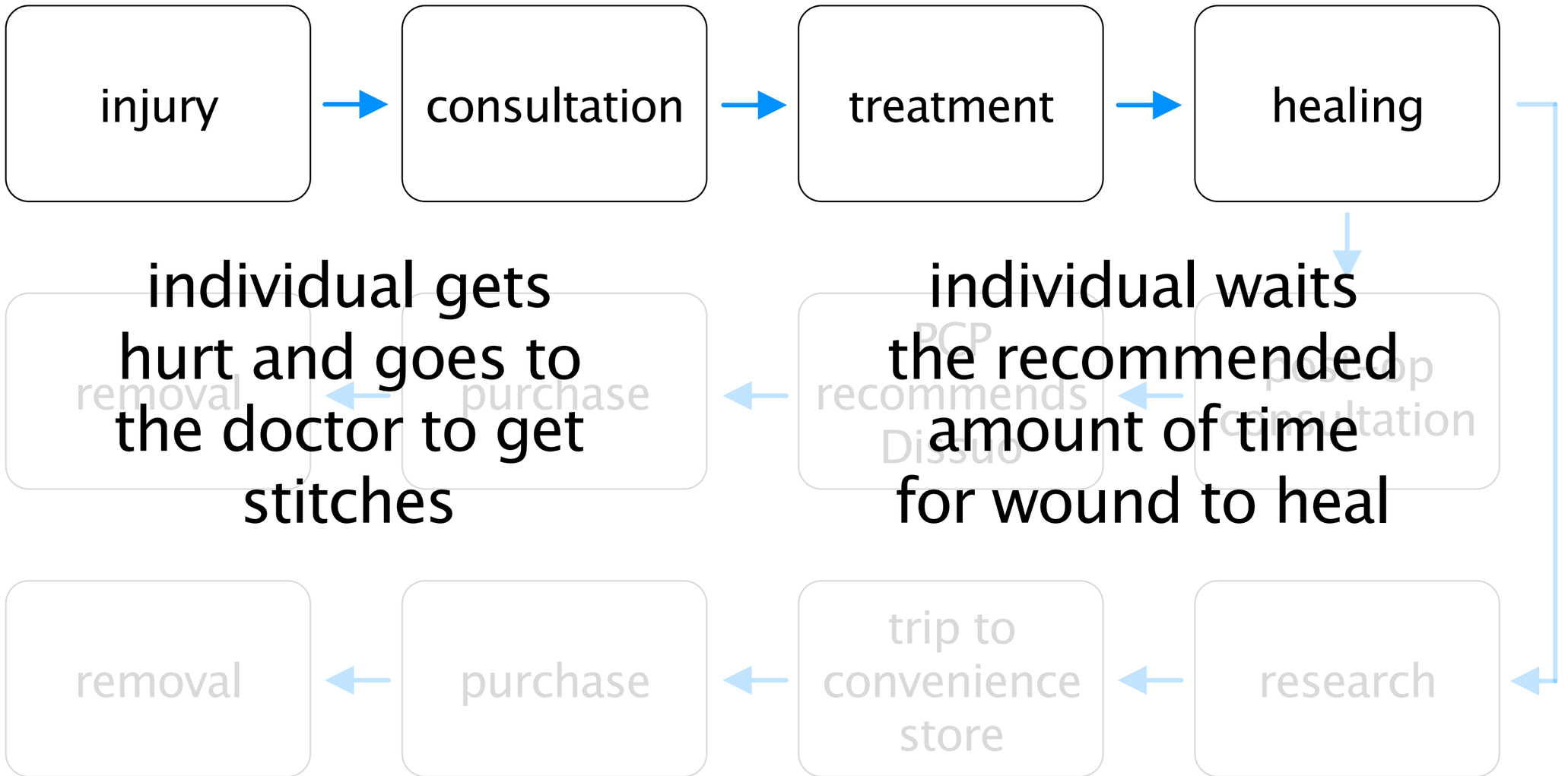
Bill, 64, a surgeon who owns a private practice in Lexington

1. My patient, John Doe, has a deep laceration on his forearm.
2. I stitch up his wound and let him know that it will be ready for removal in 8-10 days.
3. However, I have been experiencing an influx of patients calling in asking for my availability. A checkup with John might prevent me from seeing my paying patients- some of them require urgent care, so I might lose their business.
4. I explain the situation to John before he leaves, and I recommend that he use a Dissuo device to remove the stitches himself. I give him brief instructions, and I tell him to video chat me if he has questions about healing. He is ecstatic; this saves him a future trip to the office.
5. I tell him he can find the device at a convenience store on his way home or, I can sell it to him for a small fee.
6. John decides to buy one from my clinic, and my schedule frees up- allowing me to see paying patients.

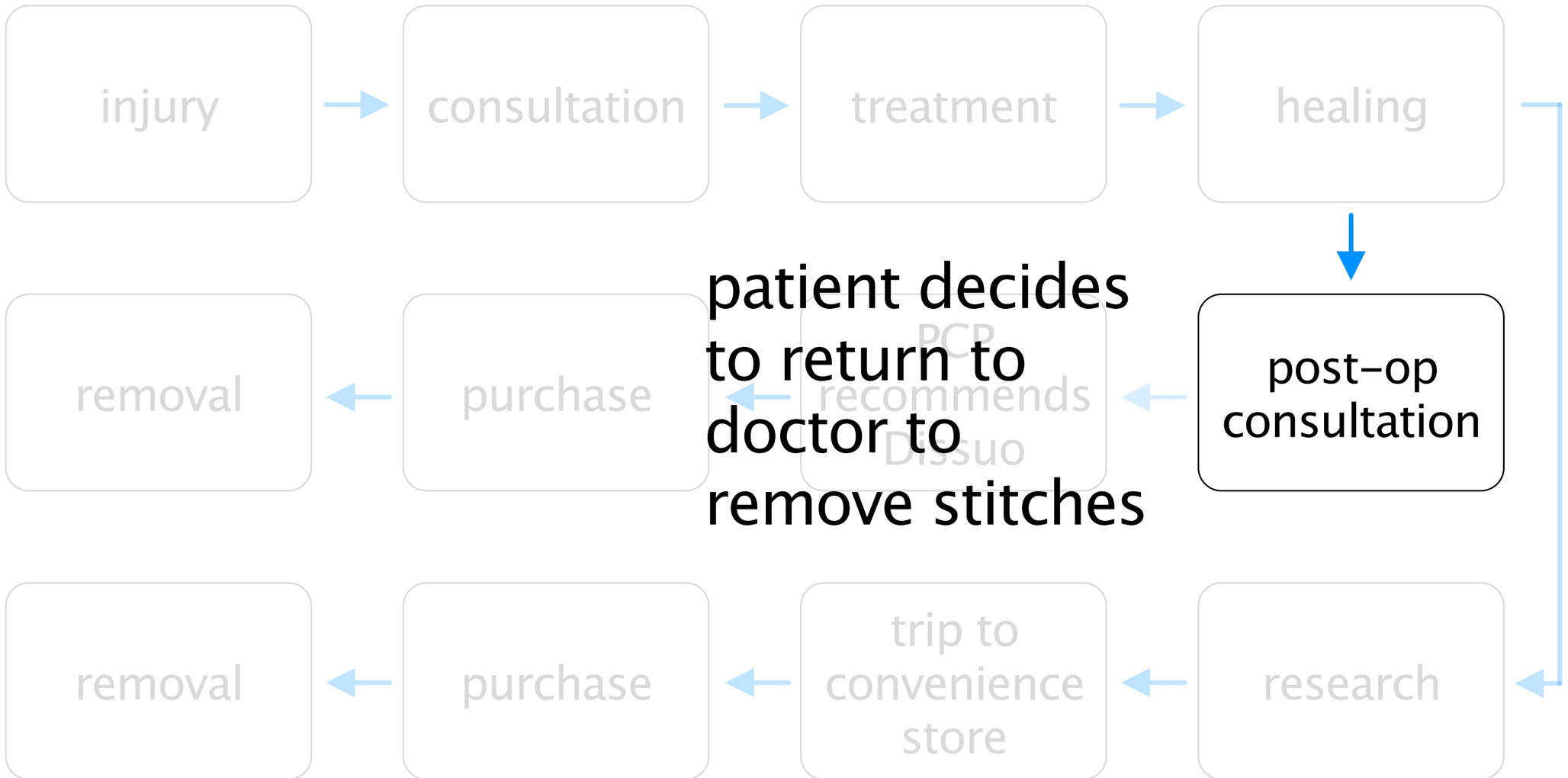
Journey Overview



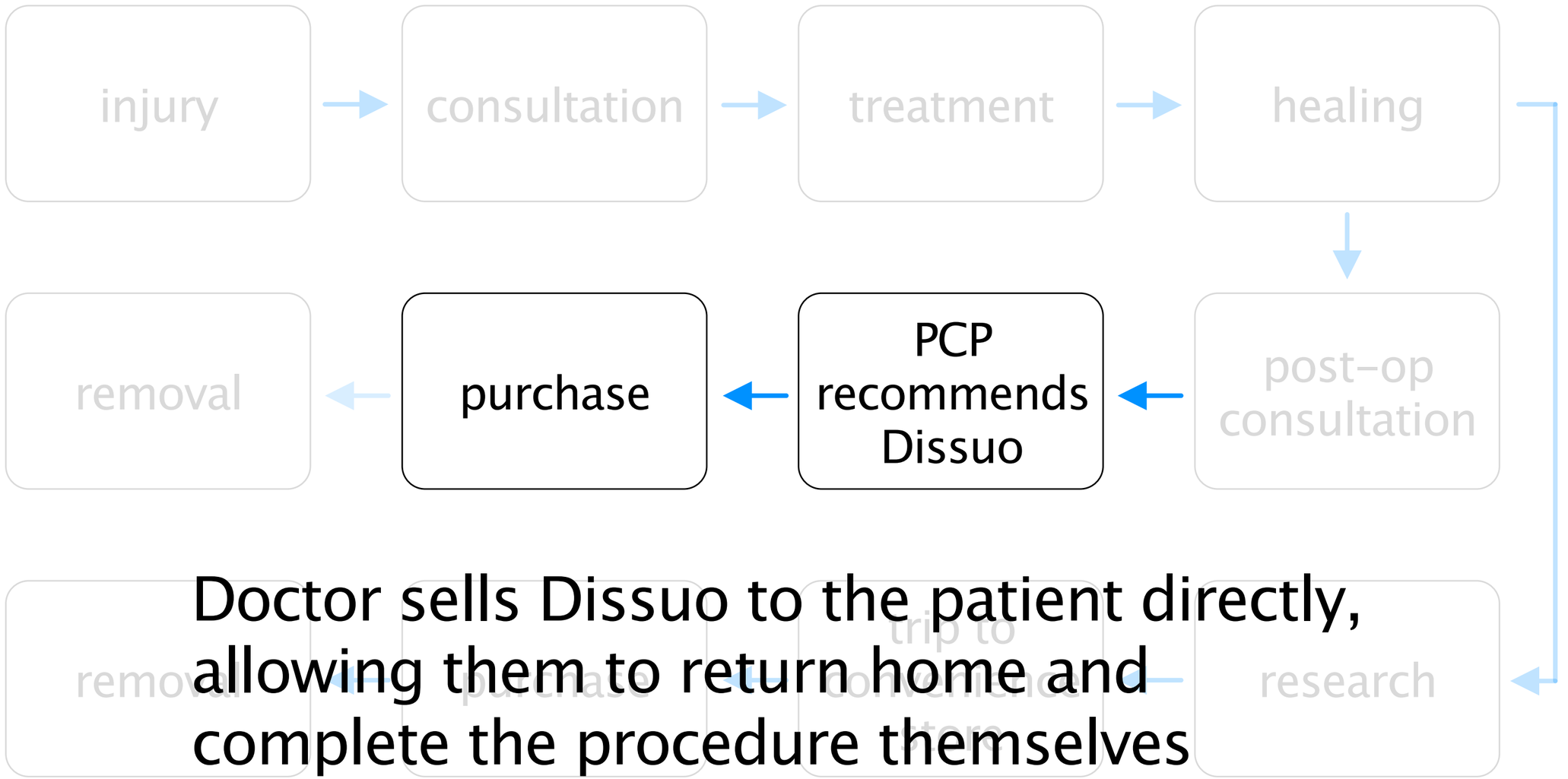
Journey: Step 1



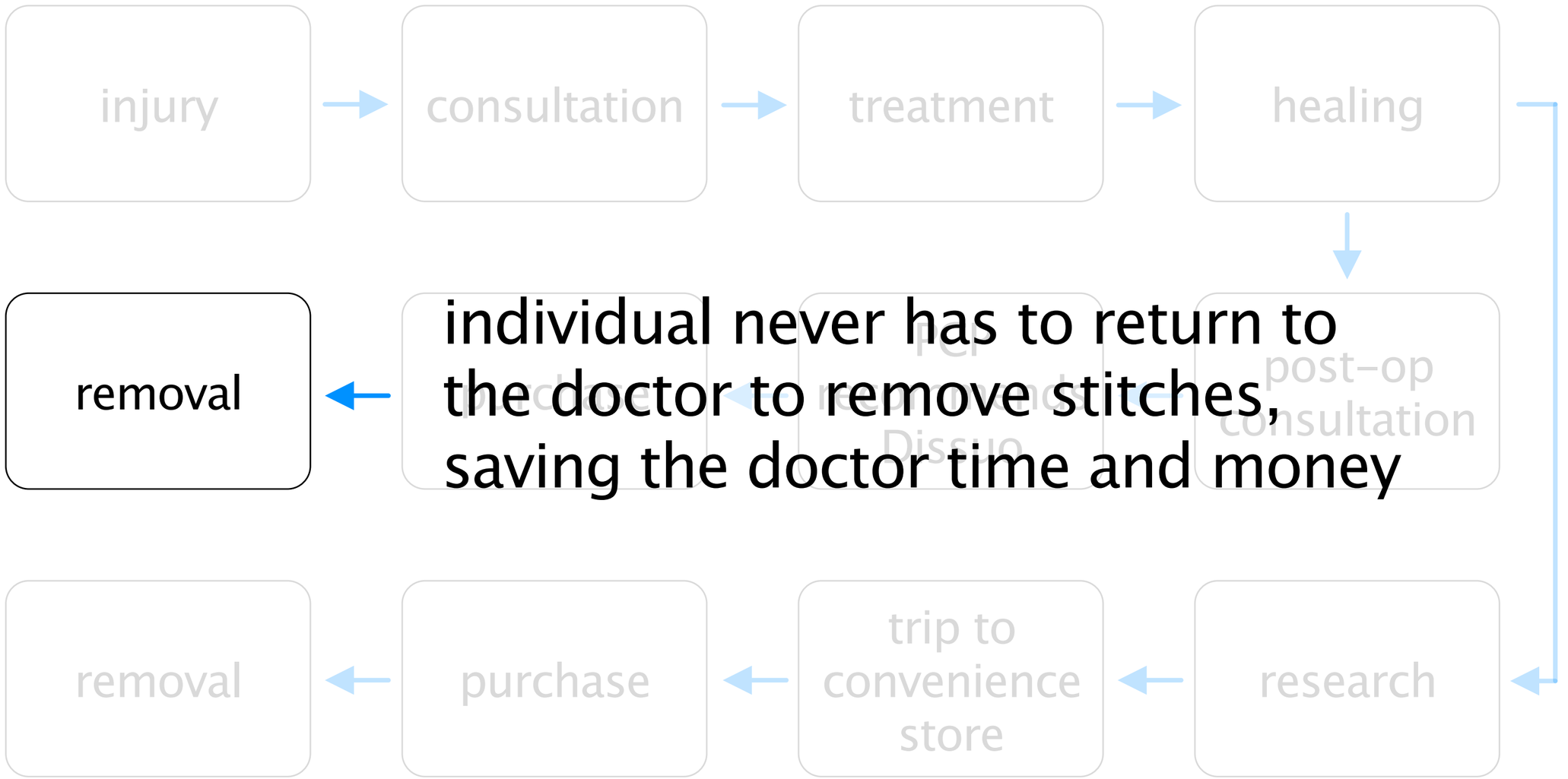
Journey: Step 2a



Journey: Step 3a

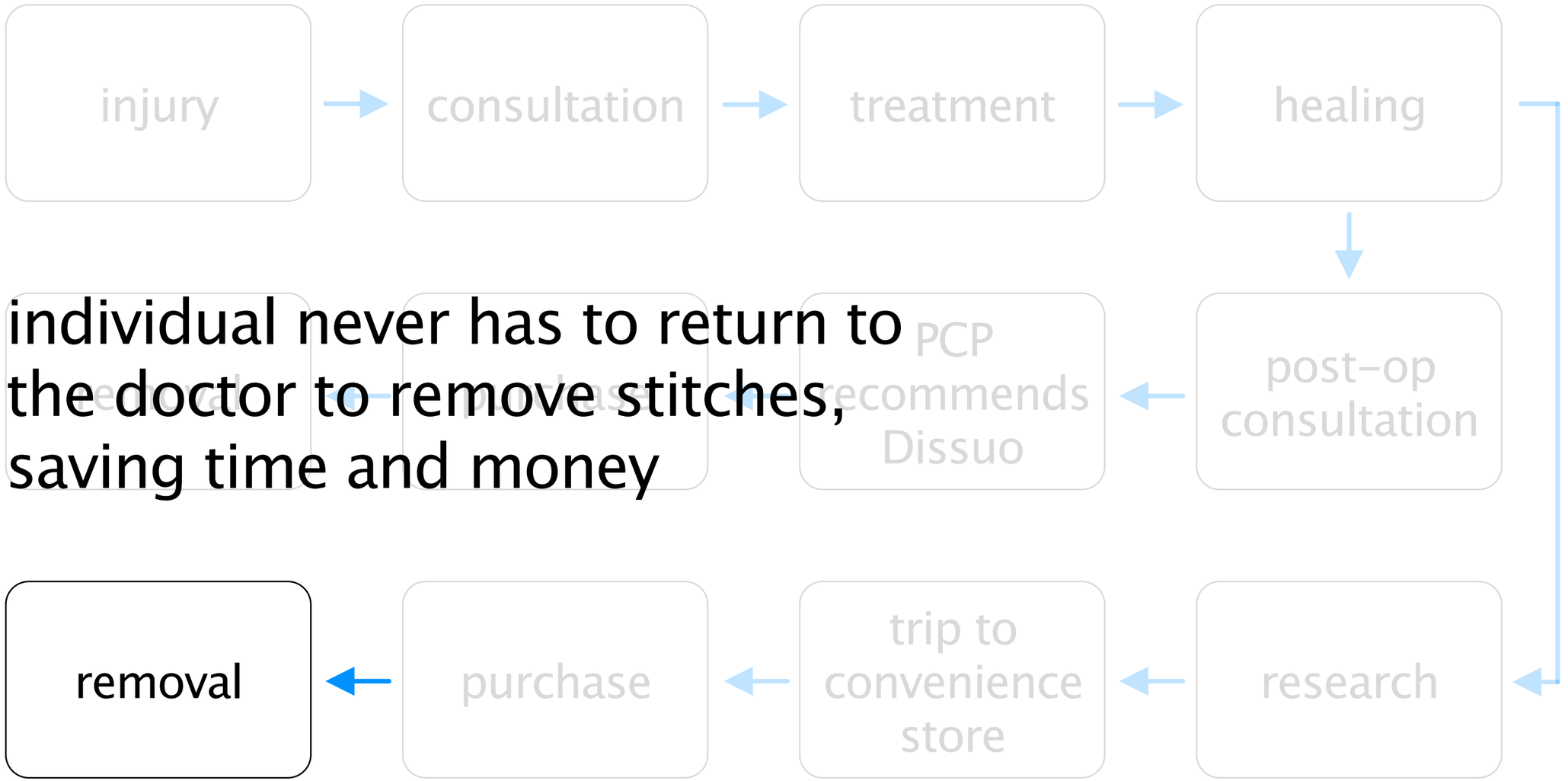


Journey: Step 4a



Journey: Step 2b

Journey: Step 3b



individual never has to return to the doctor to remove stitches, saving time and money

Potential Issues

Self-Injury

safeguards…

metal base with divot for the blade protects the skin from any contact with the blade

anti-abrasive padding underneath the base protects the wound from any irritation or further injury

comes with detailed instructions and demonstration on using the device

The enclosed and guided blade in our product imposes far less risk of injury than scissors and tweezers do when opting for self-removal

Going Forward

Market Confidence

trust in the product is key…

intuition, safety, and the instructions' details will be key in building consumer trust

the design's sleek and easy-to-use feel that has a protection against the skin surface will instill confidence in the user

FDA Approval

The distribution of a medical device requires approval from the FDA. This process is understandably tenuous but can be accurately condensed into the following steps:

- The approval process begins with a pre-market approval application (PMA) detailing a number of things, including materials, labelling, and other necessary specifications about the makeup of the product. The PMA must include a nonclinical laboratory study proving the safety of the product, and references to clinical studies performed using the product. Conclusions about device performance must also be included

- FDA review of the PMA will end in rejection if the product is deemed unsafe or if the product differs from the specifications described in the PMA

- Post approval requirements include compliance with conditions stated by the FDA upon approval of the PMA

Materials (speculation)

The device shell could consist of a hard plastic like acetal, which is cost effective and sturdy. This material is often used in hard shell casings for pipes and other medical devices, making it an ideal option for our shell.

The blade and scythe could be stainless steel.

The spring could consist of a cheap metal alloy compliant with FDA standards.

The thin non-abrasive padding on the bottom of the scythe could be nylon. Nylon is a thermoplastic silky material that can be easily morphed into working shapes, so it would provide an effective cushion below the scythe.

Price Goals

our survey feedback indicates**

85%

of respondents

would pay up to $20 for a suture removal device

57%

of respondents

would pay up to $30 for a suture removal device

Our ideal price would comfortably conform to this range, especially given the minimalist design of our product and the cheap pricing of most materials.

It's difficult to nail down a price because the price of stainless steel, the most expensive potential component for our product, is volatile and dependent on the quantity purchased.

**all of our respondents were college students

Business Propositions

- We have reached out to patent lawyers to discuss filing a provisional patent
- The next step is to begin prototyping and testing (required for FDA approval)
- Note: If we receive FDA approval, the sale and production of the device might be subject to their specified approval conditions
- An ideal future for our product includes sales to pharmacies and convenience stores but also to medical practices. This would allow us to reach both of our target groups
- Sales to medical practices offers a hidden pathway to our target audience– an exchange of the device to patients after surgery (for self–removal). This could greatly expand the reach of our product.

Sources and Surveys

https://drive.google.com/open?id=1FZVmcZ2PNoOa1RDpuhFQnqhJaBvLVUyG

Thank You!