ISSN (Online) 2456 -1304

International Journal of Science, Engineering and Management (IJSEM)

Volume 12 Issue 11 November 2025

Ergonomic and Safety-Oriented Design of an Ampule Breaking Device for Medical Applications using User-Centered Methodology

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Abstract*— This study addresses the need for a safer and more efficient ampule-breaking solution in healthcare settings. Ampules, widely used for medication storage, provide a sterile environment that safeguards drugs from contamination. Traditional methods of opening ampules, including knives, gloves, cloth, and basic devices, often lead to safety risks, glass contamination, and inefficiency. To overcome these issues, a user-centered design (UCD) approach was adopted to develop an innovative ampule breaker. This device prioritizes user safety, minimizes contamination, and simplifies the ampule-opening process by capturing broken glass particles and ensuring a clean, controlled break. Finite Element Analysis (FEA) of borosilicate glass ampules was conducted to assess different breaking mechanisms and optimize stress distribution. The ampule breaker's ergonomic design allows healthcare professionals to handle various ampule sizes (1-5 ml) efficiently, addressing key regulatory and material considerations. With an integrated cap collection system, this solution reduces injury risks and contamination, enhancing clinical workflows. The IPR was filed for the device, and it will soon be brought to the market after the required regulatory clearances and certifications.

***Index Terms*— User-centered Design, Ampule Breaking, FEA, Prototyping, ABS, TPU, Mechanism**

I. INTRODUCTION

The field of healthcare relies on precision, safety, and efficiency, particularly when it comes to handling medications. Various methods have been developed for transferring medications from their origin to usage areas, with a strong focus on maintaining sterility and dosage precision. Among these methods, the ampule has emerged as an indispensable solution in global healthcare[1]. Ampules offer a sealed environment that protects sensitive medications from contamination and environmental factors, ensuring they reach patients in the safest and most effective form. This sealed design, along with the precise dosing it enables, has cemented ampules' role as a critical component in medical storage and delivery systems worldwide. Its origins can be traced back to the early 20th century, when the need for sterile storage solutions became more apparent due to advancements in medical science and a growing focus on hygiene and contamination prevention. Glass is dominantly used in ampule production primarily due to its superior chemical inertness[2]. Unlike plastic, which can potentially leach contaminants into the contents, glass offers an impermeable barrier that protects against gas and moisture penetration. This feature is especially critical in storing medications that are highly reactive or sensitive to environmental changes.

Borosilicate glass [3] is commonly used because of its high resistance to thermal shock and chemical interactions. Its durability and transparency make it an ideal choice, allowing healthcare providers to visually inspect the contents for contamination or degradation without compromising sterility. The ability of borosilicate glass to maintain drug stability and prevent leaching has contributed significantly to the global preference for glass ampules in pharmaceutical applications. The single-use nature of ampules minimizes the risk of cross-contamination and accidental overdosing, both of which are critical concerns in healthcare settings. Their small, portable risk design makes them suitable for use in diverse environments, including hospitals, emergency rooms, and even in-field medical situations.

The conventional methods of opening ampules have long been associated with various challenges, including safety hazards, contamination risks, and inefficiencies in clinical settings. Traditional methods of ampule opening, whether using knives, hands with gloves, cloth, or basic breaking devices, have known limitations, often resulting in an increased risk of injury and potential contamination of the medication.[4-7]

In response to these challenges, a user-centered design (UCD)[8-9] approach was adopted to develop an innovative ampule breaker. This design methodology emphasizes empathy and close collaboration with end-users, allowing for iterative improvements based on direct feedback. The goal is to create a device that enhances user safety, minimizes contamination risk, and simplifies the ampule-opening process. Through comprehensive analysis and testing, various breaking mechanisms and materials were examined, ultimately leading to a design that integrates safety, efficiency, and versatility in one compact tool.

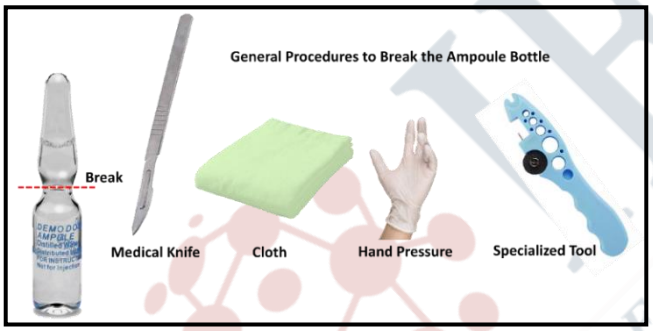
This ampule breaker is engineered not only to apply the precise amount of force needed to break the ampule's neck

ISSN (Online) 2456 -1304
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cleanly but also to prevent injuries by capturing broken glass particles. The ergonomic design ensures that healthcare professionals can operate it with ease and confidence, even when handling multiple ampules in quick succession. By combining a flexible grip with a disposable cap collection system, this solution addresses both functional and safety requirements, presenting a novel and much-needed advancement in ampule-handling practices. The Ampule Breaker has been meticulously designed to accommodate ampule bottles ranging from 1 ml to 5 ml in capacity, providing versatility to meet a wide range of medication needs. In the later research detailed study was performed using UCD methodology for the empathy, prototyping & testing of the breaker. Since it is a medical device, regulatory considerations in terms of materials used, safety, reusability, and other important parameters were considered during the design & development of the ampule breaker. Later IPR was filed for the same.

II. EMPATHY STUDY OF CONVENTIONAL AMPULE BREAKING METHODOLOGIES

Conventional opening ampules often lead to cuts, injuries, or contamination. The various methods were adopted before and are still used to break the ampule (Fig. 1). An in-depth empathy study was conducted to know the actual problem, and literature was referred to translate the solutions for the situation.



(a)



(b)

Fig. 1: Various Traditional method for breaking the Ampule (a) Knife, cloth, gloves, and opening tools (b) Injuries occurs due to breaking the ampule

Various methods of breaking were reported in the literature and online databases [10-12], as it is a traditional method for giving medicine and is widely used. The ampule method, generally practiced in hospitals, was:

- Using the Knife: One of the conventional methods paramedics employ to open ampules involves using a specialized ampule opener or breaker, which resembles a small knife with a sharp, pointed edge. To break the ampule, the paramedic places the neck of the ampule against the ampule opener and exerts pressure to snap it open. While efficient and swift, this method carries a potential risk of injury if not executed carefully. There is a possibility of glass splinters scattering during the process, necessitating cautious handling.
- Using the Hand with Gloves: Paramedics may also employ their gloved hands to open an ampule safely. They wear protective gloves from materials such as latex or nitrile, which protect against sharp glass edges. With their gloved hands, they securely grasp the ampule by the neck and apply controlled force to snap it open. This approach is simple and easily accessible but involves some risk, mainly if the gloves are not sufficiently thick or the paramedic is not cautious enough. There is a potential for glass splinters or injury if the ampule breaks unevenly or spillage of the medicine.
- Using a Thick Cloth: Another traditional technique is to use a thick cloth or gauze to open the ampule. Paramedics wrap the neck of the ampule in the cloth, creating a protective barrier between their hands and the glass. They then apply force to break the ampule. This method adds a layer of safety, as the cloth helps contain any glass shards that might result from the breakage. However, ensuring a clean break and preventing uneven fractures may require more effort.
- Using a Device for Breaking: In certain situations, paramedics rely on specialized ampule breaker devices. These devices typically contain a plastic or metal holder that firmly secures the ampule. The paramedic then applies pressure to the device, resulting in the breaking of the ampule. This method is quick, but the device has limited capability for breaking the different-sized ampules or has an open end, which can be harmful and injure the hand.

Each of these methods offers its own set of advantages and drawbacks. The choice of method depends on the specific circumstances, the availability of equipment, and the paramedic's training and personal preference. The injury associated with breaking an ampule can occur in several ways, each presenting its own set of risks. Firstly, when applying force to break the ampule, the sharp edges created during the process can cause cuts or lacerations to the skin. These sharp edges are often difficult to handle safely, especially if the person's grip slips or if they apply excessive force.

Secondly, upon breaking, the glass particles generated from the shattered ampule can become airborne or settle on surfaces nearby. If these particles come into contact with the

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skin, they can penetrate the surface and cause abrasions or puncture wounds. Additionally, if glass particles are inadvertently ingested or enter the eyes, they can cause further injury and discomfort.

Lastly, the broken cap of the ampule can also pose a risk of injury. If not handled properly, the sharp edges of the broken cap can cut or puncture the skin. Moreover, if the broken cap is left exposed or disposed of improperly, it can present a hazard to individuals in the vicinity, potentially leading to injuries if stepped on or mishandled.

Overall, the process of breaking an ampule involves various potential hazards that can result in injuries ranging from minor cuts to more severe lacerations or puncture wounds. Therefore, it is crucial to implement safety measures and protocols to minimize these risks and ensure the safe handling of ampules in healthcare settings. After considering the above facts, there is a need for a safe ampule breaker that can even safeguard broken glass pieces from the bottle and break the ampule easily. Since this problem is associated with a specific user group, their experience & pain points, and also requires a close interaction with them for the iterative process of designing a user centric design methodology, it is adopted to develop this product.



(a) *(b)*

Fig. 2: Parts of an ampule bottle and (b) various sizes available

The ampule bottle is made of clear glass, which is brittle in nature. The major parts were the bottle head, i.e., the upper part; the neck, i.e., the weakest part, which is broken to open the ampule; and the lower part, i.e., the body of the ampule (Fig. 2). The bottle comes in various sizes and shapes based on the amount of the drug chemical inside it. By closely interacting with the user and the problem statement is defined "Develop a user-friendly ampule breaker with an integrated glass cap collection, designed for quick and efficient breaking of ampules of various capacities, prioritize safety by minimizing injury risks and contamination concerns." Various breaking mechanisms were analyzed in the next section to design the breaking device.

III. DESIGN & DEVELOPMENT OF AMPULE BREAKER

A. Comparative study of Different forces for breaking the Ampule Bottle

The various mechanisms for breaking the ampule were discussed in detail, and numerical analysis was performed to determine the stress and deformation behaviour of the ampule bottle while applying various forces. The finite element (FE) [13] model utilized in the nonlinear structural analysis aimed to simulate the behaviour of the ampule bottle under various loading conditions. The ampule bottle material properties, i.e., of "borosilicate glass", were incorporated into the model to ensure realistic material behavior (Table 1)

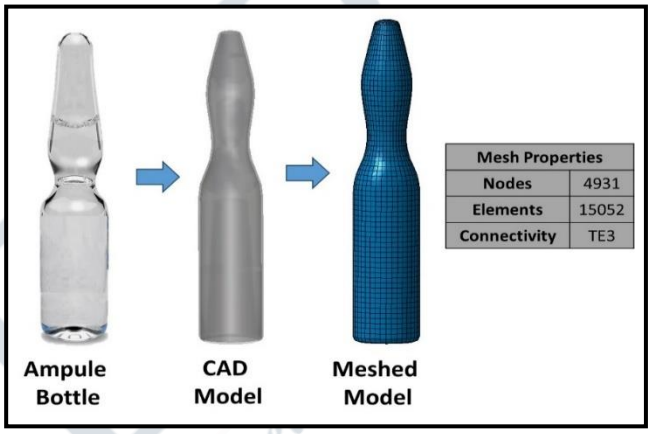


Fig. 3: The CAD and Meshed model for the numerical analysis of the ampule bottle

Quadrilateral meshing is performed over the FE body with a mesh size of 1 mm. This meshing strategy ensures that the model accurately captures the structural behaviour of the ampule bottle while maintaining computational efficiency. Fig. 3 shows the basic CAD model and the meshed body used for further analysis of the breaking mechanism.

Table 1: Properties of Borosilicate Glass

Property Borosilicate Glass	Value
Young's Modulus	83 GPa
Poisson's Ratio	0.3
Density	2330 kg/m³
Yield Strength	1.2×1081.2×108 N/m²
Coefficient of Thermal Expansion	3.3×10−63.3×10−6 /Kdeg

Considering the brittleness of the material and the regulatory compliance for a medical device, different mechanisms based on the applied force and directions over the bottle were evaluated. Some of the analyzed forces may not be used to break the ampule bottle, but performing an FE analysis of them over the bottle helps in understanding the bottle's response to different types of mechanical stress and different failure modes. Understanding how other forces affect the bottle can help refine the breaking process for cleaner or more controlled breaks. As per the literature [14],

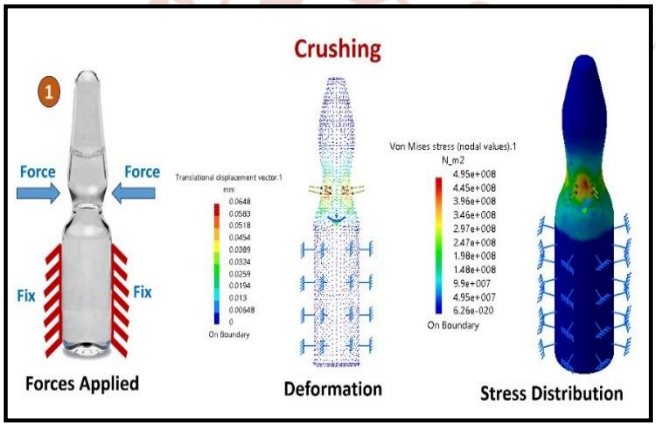
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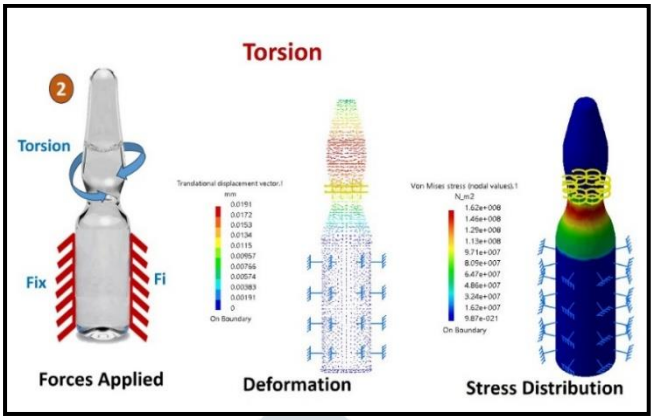
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the force required for breaking the ampule is around 45N, and so the FEA was performed according to that.

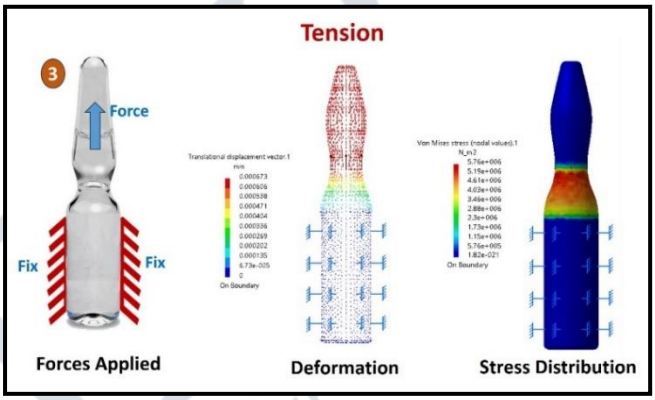
- Crushing: The technique of crushing the bottleneck by applying pressure to the ampule's neck, as shown in Fig. 4(a). It effectively breaks the cap and necessitates minimal equipment. However, this method carries notable disadvantages, including the generation of numerous glass particles, a risk of hand injury due to the applied force, non-uniform crushing, and the potential for contamination of the ampule's contents.
- Torsion: Applying a torsion force to the ampule's neck is advantageous as it tends to distribute stress more evenly, but this method also has disadvantages. Securing the upper part for torsion can be challenging, resulting in uneven breakage and technical complexities. Also, rotation of the upper part of the bottle tends to enhance the exposure of the hand to the broken glass, which may risk injury (Fig. 4(b)).
- Tension: Applying the tension loading, i.e., holding the neck and pulling outwards, this method offers the advantage of uniform stress distribution across the ampule's structure. Nonetheless, it presents its own set of drawbacks, including uneven breakage and difficulties associated with proper ampule handling since the material is brittle, and sudden tension may break the bottle at the holding point (Fig. 4(c)).
- Shearing: This technique involves applying force from a single direction to the ampule, which is advantageous due to its minimal equipment requirements. However, this method
- Cutting: The widely practiced method of using a knife to break the ampule has advantages, such as efficiently concentrating stress. However, it has notable disadvantages, particularly a safety risk that can cause hand injuries and limited operation to manual handling (Fig. 4(e)).



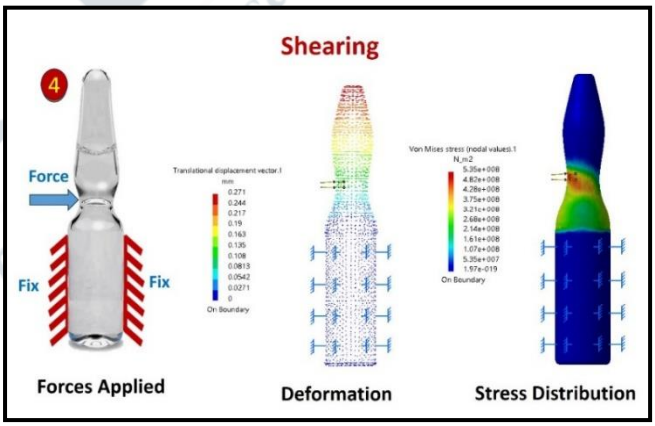
(a)



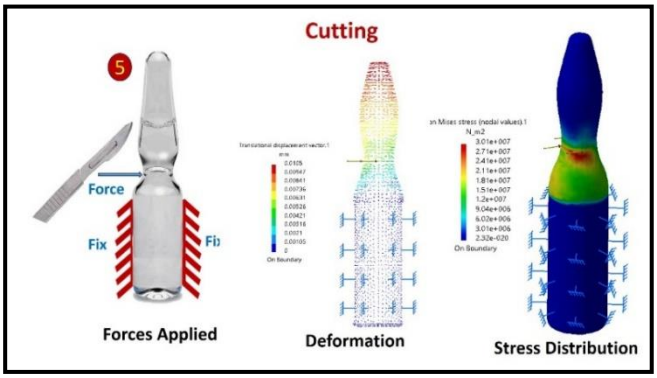
(b)



(c)



(d)

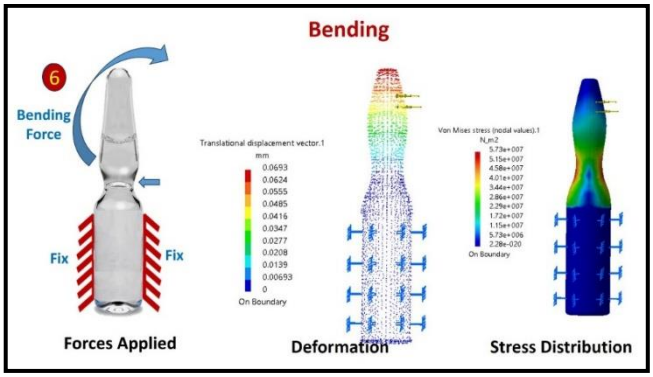


(e)

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(f)

Fig. 4: Different types of breaking forces for opening the ampule bottle: (a) Crushing, (b) Torsion, (c) Tension, (d) Shearing, (e) Cutting, (f) Bending.

- Bending: This method efficiently applies compressive and tensile forces to the ampule, leading to an effective and clean break. The bending load mechanism is found to be the most suitable option due to its unique advantages. Since the ampule bottles typically have a thinner neck, this concentrates stress at this point when a bending force is applied. This concentrated stress makes the neck more likely to break compared to the thicker bottle body. Additionally, borosilicate glass, while strong in compression, is weaker in tension. Bending creates a combination of tension and compression within the material. The tension on the outer surface of the neck during bending exceeds the material's tensile strength, leading to breakage. Bending mechanism for breaking addresses the key issues other mechanisms face, such as the generation of glass particles, hand injury risks, non-uniform breaking, and contamination of ampule contents. It introduces a more efficient and safer approach to ampule breaking, making it the optimal choice.

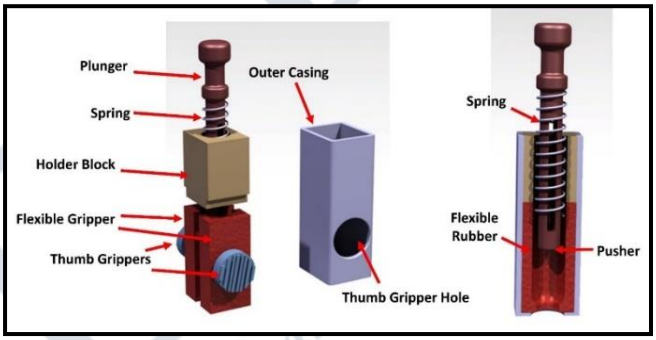
Fig. 4(f) shows the breaking force and the ampule bottle's stress distribution. This breaking mechanism is utilized to prototype the device for further product development.

B. Prototyping of Ampule Breaker

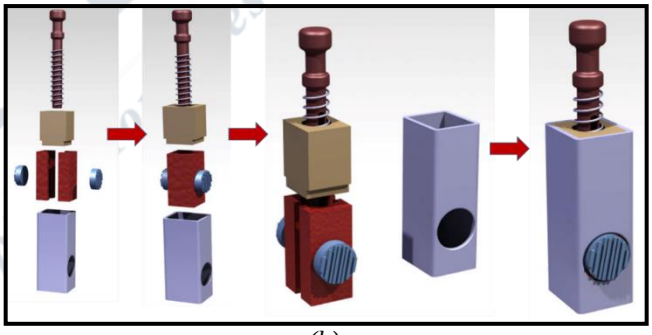
Before prototyping, various important points were considered, i.e., uniform force distribution over the holding mechanism of the ampule, applying a critical load only over the weakest part, i.e., the neck of the bottle, removing the broken glass cap away from the hand to prevent injury, the material used must be biocompatible, the mechanism must be easy to implement and use, easy to carry and a single solution for breaking multiple size bottles to enhance universality. This reduces the risk of injury and minimizes the generation of glass particles that can contaminate the medication or cause harm to healthcare professionals.

Various possibilities for breaking the ampule by applying the bending load over the neck were explored, and it was found that the flexible and adjustable gripping mechanism can apply a uniform pressure over the bottle while holding, along can also accommodate different sizes of bottle heads. A flexible material, Thermoplastic polyurethane (TPU) [15], was shortlisted for making the flexible gripping mechanism. TPU is a biocompatible material with minimal cytotoxicity, ensuring it doesn't harm living tissues [16]. It is contamination-free and suitable for medical devices, and its flexibility, durability, and washability make it ideal for maintaining hygiene and comfort in healthcare settings.

A cap-holding mechanism was devised to separate the broken cap pieces from mixing or causing any injury, which can easily store the cap after breaking. A plunger-type storage mechanism was combined with the holding mechanism, which can be easily disposed of after breaking. After taking care of the ergonomic aspect, the above features were combined to form an ampule breaker with a disposable mechanism. The parts and their assembly are shown in Fig. 5.



(a)



(b)

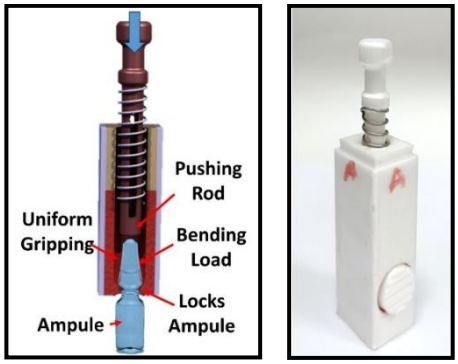
Fig. 5: CAD illustration of the Ampule breaking device (a) various parts and (b) assembly

The mechanism was placed inside the casing, and the thumb grippers were placed to hold and apply uniform pressure over different sizes of bottles. The spring-based disposable mechanism makes it easier to use and is superior to the existing methods. Fig. 6 shows the holding mechanism along with the prototype developed. The outer part was made of ABS material [17], which is biocompatible and widely used in the development of medical devices.

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(*a*) (*b*)

Fig. 6: Ampule bottle breaking (a) holding mechanism (b) Prototype

IV. EVALUATION & IMPLEMENTATION

A. Usage steps

Fig. 7 shows the detailed steps for using the ampule breaker; the steps were holding the breaker in hand properly, inserting the ampule from the bottom hole with the neck at the outer periphery of the hole, pressing the thumb gripper for proper holding and pressure, and applying a bending force over the ampule; the bottle breaks from the neck. The cap will be stored inside the casing and can be disposed of after breaking. The cap will not fall, while applying a uniform loading, the glass particles were also less, which makes the whole system more efficient than other methods. The breaker can be stored and sterilized easily.

A user safety study was performed over the group of resident doctors, learners & the medical students who have a daily interaction with the ampule bottles. The method was compared with the traditional practice of breaking the ampule used in hospitals. As shown in Fig. 8, the study shows that the device developed is safe, easy to use, and solves the problem of breaking the ampule without injury.

B. Novelties of the device

The Ampule Breaker introduces several novel features that. Set it apart from traditional ampule-opening methods. These innovations include (Fig. 9):

- Cube-Shaped Design: The Ampule Breaker's distinctive cube shape offers a secure and ergonomic grip, ensuring user comfort during operation.
- High-Density Semicircular Twin Rubber Grips: At the bottom of the device, specialized high-density semicircular twin rubber grips made of TPU are integrated. These grips firmly hold the ampule bottle in place and apply circumferential pressure, ensuring stability and controlled breaking, along with easy sterilization.
- Specialized Opener Mechanism: A unique, specialized opener facilitates the application of a minimal force in the opposite direction to the ampule bottle. This, combined with the grip provided by the rubber arrangement, results in a clean and precise ampule breakage.
- Versatile Ampule Compatibility: The Ampule Breaker has been meticulously designed to accommodate ampule bottles ranging from 1 ml to 5 ml in capacity, providing versatility to meet a wide range of medication needs.
- Efficiency and Time Savings: Traditional methods of breaking ampules can be time-consuming and inefficient, especially when dealing with multiple ampules. The ampule breaker streamlines the process by ensuring clean and precise ampule breaks with minimal effort, saving valuable time and improving workflow efficiency.
- Cap Disposal Mechanism: Once the ampule is successfully broken, the broken cap is securely held within the device by a piston mechanism. An upper piston arrangement is incorporated to ensure convenient disposal, allowing for easy ejection of the broken cap. Additionally, the Ampule Breaker features a storage capacity for up to two bottle caps, maintaining a tidy workspace and enabling efficient disposal after breaking ampules.
- Ambidextrous Design: The device's ambidextrous design allows right- and left-handed users to operate comfortably, enhancing its usability.
- Hygiene and Contamination Control: Contamination is a significant concern in medication administration. The design minimizes the risk of contamination by securely holding the broken ampule cap inside the device, allowing for easy and hygienic disposal.
- Easy to use and implement: The design is simple and easily acceptable in the current practices.

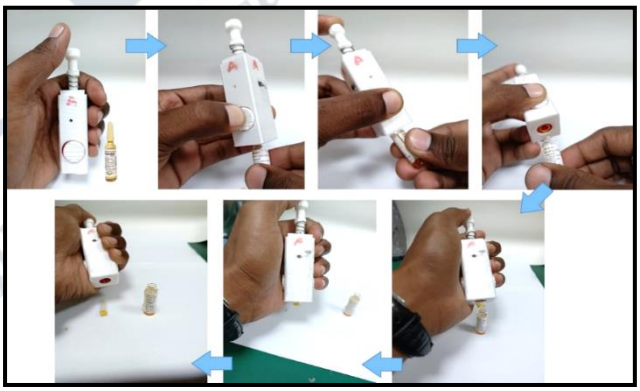


Fig. 7: Usage steps of the Ampule breaker

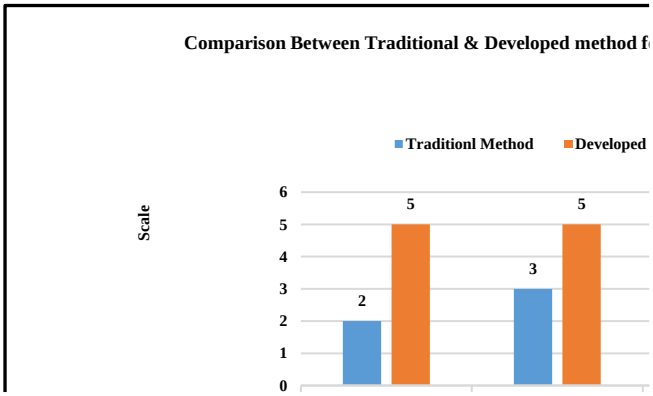


Fig. 8: Comparison Between Traditional & Developed Methods for Breaking the Ampule Bottle

ISSN (Online) 2456 -1304

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Fig. 9: Novelties of the Device Developed

Fig. 10 shows the testing results of the ampule-breaking device. The results show that the breaking is uniform, and the edges are clean, ensuring that minimal glass particles are generated during the breaking. IPR was filed for the device having application number 202311047382 [18]. Currently, the system is in a testing phase. As a Class A medical device, once certified and after regulatory approval, the product will be launched in the market for use.



Fig. 10: Ampule breaker and its testing results for breaking the bottle

V. CONCLUSION

In this study, a specialized device was designed and developed for breaking the ampule bottles using the User Centered design methodology. It offers a solution that prioritizing user safety and operational efficiency. The Ampule Breaker addresses longstanding challenges associated with conventional ampule-opening methods. The device's unique combination of features, including specialized rubber grips, thumb grippers, a cap-holding mechanism, an enclosed casing, and an ambidextrous design, underscores its versatility and user-friendliness. Extensive research and development have resulted in the selection of the bending load mechanism as the most efficient and contamination-free approach to ampule opening. The securing of intellectual property rights further reinforces its innovative nature. Once certified, this device promises to have a substantial impact on healthcare practices, providing healthcare professionals and patients with a safer, more efficient, and user-friendly solution for ampule opening.

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