

## ENGINEERING PROGRESS: DEVELOPING ADVANCED DELIVERY SYSTEM FOR IMPLANTING BIORESORBABLE NASAL IMPLANT

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### ABSTRACT

*This research article presents a novel delivery system consisting a novel delivery tool, that facilitates the placement of a nasal implant at the treatment site. The proposed cartridge arrangement aims to eliminate operator mishandling of the implant while loading it directly into the delivery system. The implant is delivered in a sterile condition and separately packaged within the cartridge cavity, ensuring its integrity. The cartridge is designed to be assembled with other supporting delivery tools of the system, enabling efficient and accurate implant delivery to the patient's treatment site. The primary application of this delivery system is focused on delivering a bioresorbable nasal implant into the nasal cavity. The purpose of this implant is to support the nasal valve and enhance breathing by regulating inhalation and exhalation. The "Y" shape end of the implant ensures secure anchoring between nasal tissue and nasal bone, while the remaining part supports the nasal valve, providing comfort during breathing. This research introduces a novel approach to delivering a nasal implant at the target site, offering an improved delivery method for enhancing nasal function and patient well-being.*

**KEYWORDS:** *Bioresorbable, Nasal Implant, Cartridge and Delivery System*

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### Article History

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### INTRODUCTION

Nasal valve collapse (NVC), also known as nasal valve stenosis, is a common cause of nasal obstruction. The nasal valve, which is the narrowest section of the nasal airway, can become weakened, leading to difficulty in breathing. Various approaches have been employed to address nasal valve collapse, including the use of nasal valve dilators, rhinoplasty, and strips. Nasal valve dilators can be applied externally or worn internally to alleviate the condition. While rhinoplasty can treat nasal valve collapse with or without grafts, it does not always address the underlying anatomical obstruction. Furthermore, current technologies have raised concerns about post-implantation inflammation, potentially caused by mishandling of the small implant during the loading process. As during the preparation process, the operator is required to delicately retrieve the implant using forceps from a tray and subsequently manually load it into the delivery system. This procedure, however, has the potential to compromise the structural integrity of the implant. As a consequence, such mechanical interference might lead to post-implantation inflammation.

To address these challenges, a novel delivery tool has been developed, offering a cartridge-based approach that reduces the risk of implant mishandling and ensures direct delivery to the patient's treatment site. This innovation aims to provide nasal cartilage support, improve breathing, and minimize edema, inflammation, and ulcers. The implant utilized in

this approach is composed of bioresorbable Poly (L-lactide-co-D-lactide) copolymeric material, promoting nasal valve patency. Over a period of 18 to 24 months, the implant naturally deteriorates within the body.

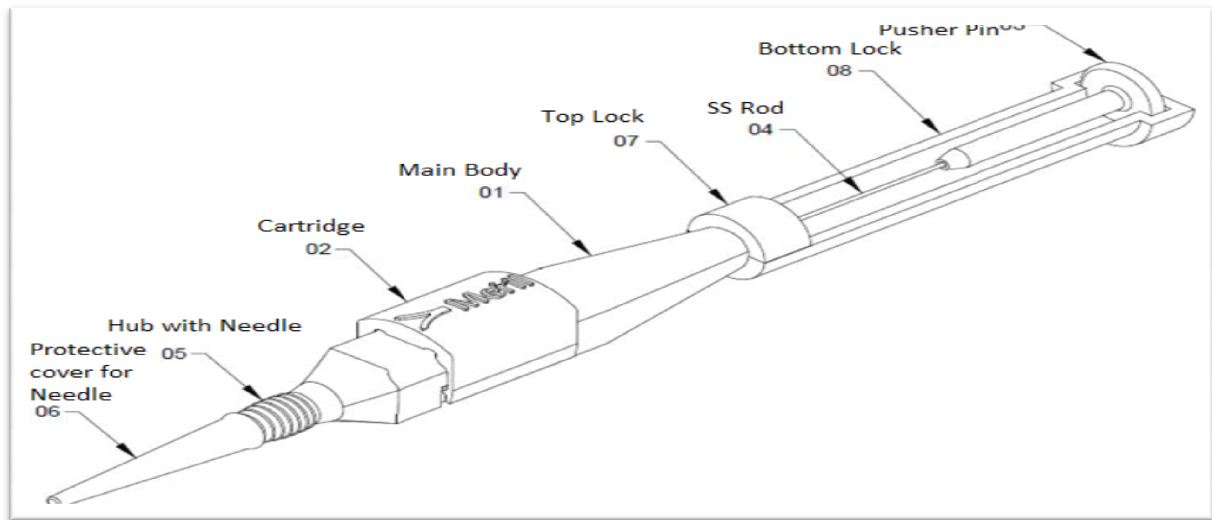
The distal end of the implant features a "Y"-shaped arm, while the proximal end is a ball end. Additionally, the device is coated with therapeutic agents to mitigate surgical effects and scar tissue formation. The delivery system itself consists of a cartridge arrangement, ensuring proper handling during implant loading and direct delivery to the treatment site. The cartridge cavity facilitates the crimping of the implant's "Y"-shaped end, guiding it towards the needle for deployment.

Moreover, the delivery system incorporates a needle with a hub attachment, simplifying the attachment process while maintaining the alignment of the inner traveling path. The distal portion of the needle possesses a sharp bevel end, facilitating easy puncture of the nose for insertion and transport of the implant to the treatment site. To accurately position the implant within the nasal anatomy, a marking strip is employed to mark the skin prior to the treatment.

The current treatment approach involves using surgical cartilage to aesthetically support the collapsible nasal valve. However, patients often experience discomfort with this method. To address nasal valve collapse, a leading cause of nasal obstruction, a new research article presents an innovative solution. This approach utilizes a bioresorbable implant and advanced delivery tool to provide nasal cartilage support, enhance breathing, and decrease complications like edema, inflammation, and ulcers. The integration of a cartridge-based system improves handling and delivery, while added elements like therapeutic coatings and a marking strip synergistically enhance treatment effectiveness.

## **MATERIALS AND METHOD**

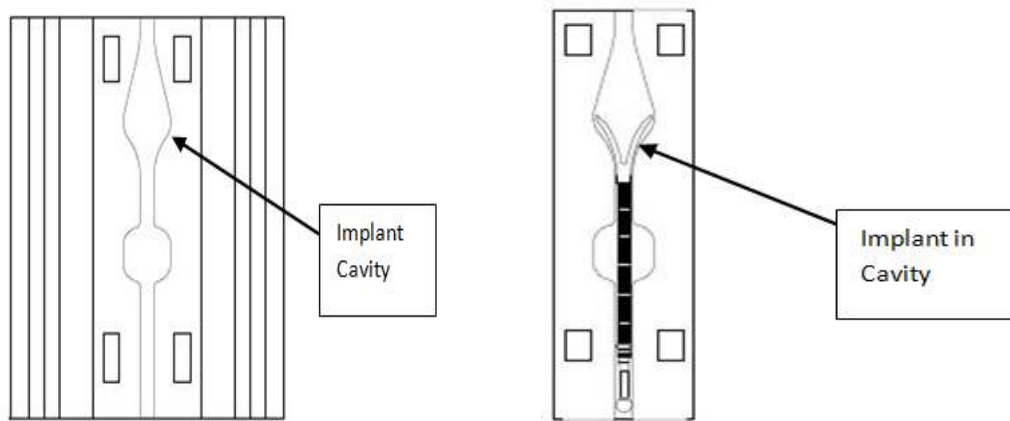
A specialized delivery instrument is employed to administer the bioresorbable nasal implant effectively. This delivery system, as illustrated in Figure 01, comprises several integral components. These include: 1) the main body, 2) the cartridge, 3) the pusher pin, 4) the stainless steel (SS) rod, 5) the needle hub, 6) the needle protective cover, 7) the top lock, and 8) the bottom lock. Each of these components serves a distinct purpose in the implant delivery process. The delivery system encompasses various subassemblies, namely the needle, pusher rod, and cartridge assemblies. The needle assembly involves bonding the needle and hub together using an appropriate bonding method. Epoxies and cyanoacrylate adhesives are utilized for this purpose. The 16G needle is bonded to the hub, with the needle's proximal end possessing a rough texture and the hub featuring internal grooves that enhance the bond strength between them. The grooves on the hub serve primarily for grip and aesthetic purposes. Similar procedures are followed for the pusher rod and SS rod sub-assembly as those used in the needle hub assembly. The pusher rod also possesses internal grooves, while the proximal end of the SS rod exhibits roughness to reinforce the bond between the pusher rod and the SS rod. The grooves on the hub and pusher rod measure approximately 0.2 to 0.3 millimeters in size. To ensure a smooth crimping and deployment process that minimizes harm to the implant, the distal end of the SS rod is flattened and coated with a hydrophilic material. This coating serves to reduce friction during insertion, thereby safeguarding the implant and promoting a smoother overall procedure.



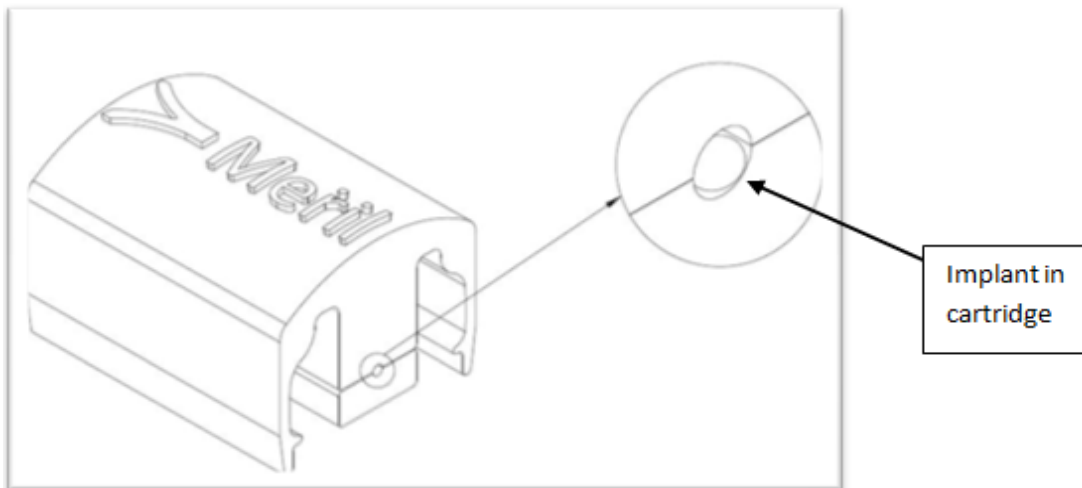
**Figure 1: Complete Assembly of the Delivery Tool System.**

The current invention incorporates a locking mechanism situated on the outer diameter of the pusher rod. This pusher rod seamlessly fits into the handle slot, located on the inner diameter of the handle, and smoothly glides through it. To facilitate the gradual deployment of the implant at the treatment site, the slot is ingeniously designed to resemble a flash symbol. The flash slot is available in two different lengths, each serving a distinct purpose. The first slot, of sufficient length, allows for crimping and pushing the implant all the way to the needle, thereby preparing the delivery instrument for the implant's deployment. The second slot, shorter than the initial slot, aids in pushing and deploying the implant to the precise treatment location. During the insertion process, this locking device effectively prevents the pusher rod from dislodging from the handle. It is important to note that only the "Y"-shaped end of the implant, acting as an anchor at the nasal bone position and providing support to the upper and lower cartilage through a cantilever effect, will be deployed using the delivery instrument. Furthermore, this locking arrangement ensures the pusher rod remains securely attached to the handle throughout the needle's tunnel-creation operation, firmly securing it in the deployed position.

For user convenience, the implant is conveniently supplied in a pre-loaded cartridge, featuring the expanded "Y" shape within its cartridge cavity. This cartridge consists of multiple components, including chambers for implant insertion in both the top and bottom cartridges, along with a locking mechanism to assemble them. The presence of cavities in the top and bottom of the cartridge, as depicted in Fig.02, facilitates easy insertion of the implant into the cavity, as demonstrated in Fig.03, subsequently triggering the crimping of the implant's "Y"-shaped end. After inserting the implant into the bottom cavity of the cartridge, it can be securely locked in place using the top cartridge. The locking mechanism of the top cartridge is thoughtfully designed to avoid interfering with the implant while effectively securing the top and bottom cartridges together.



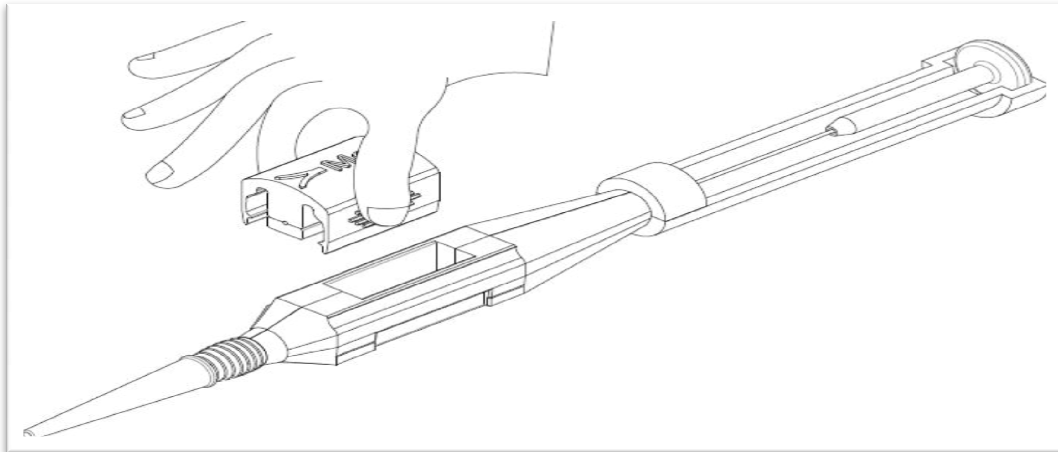
**Figure 2: Cavity for Implant into the Cartridge** **Figure 3: Implant Inserted into the Cartridge.**



**Figure 4: The Loaded Implant in the Cartridge Cavity.**

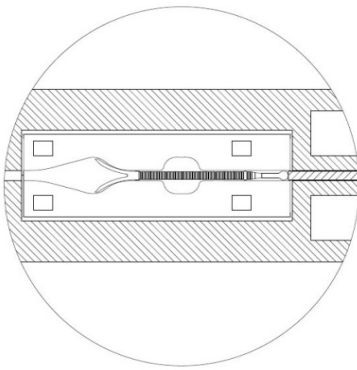
In accordance with Figure 04, the cartridge and implant will be combined. Due to the specific characteristics of the implant material, this cartridge together with implant assembly is provided as a separate kit. To safeguard the integrity, strength, and flexibility of the implant, as well as protect it from any detrimental effects caused by the environment or moisture, the assembly is vacuum-sealed within an aluminum pouch.

The cartridge possesses a wing-like structure, which facilitates the locking of the cartridge with the handle. The handle itself is adequately flexible to regain its original position and secure the cartridge. When inserting the cartridge into the handle cartridge cavity, as depicted in Figure 05, the wings of the cartridge will securely engage upon gently pushing it into the handle cavity. This prepares the delivery tool for subsequent steps. Furthermore, the cartridge is designed to enable easy locking and unlocking from the handle.

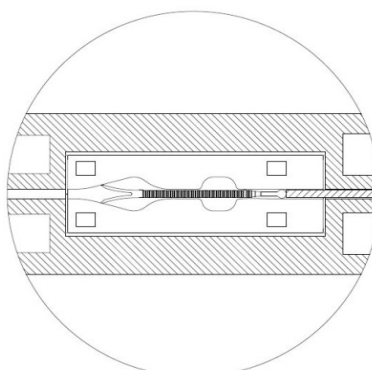


**Figure 5: Insertion of the Cartridge Containing Implant in Handle Cartridge Assembly.**

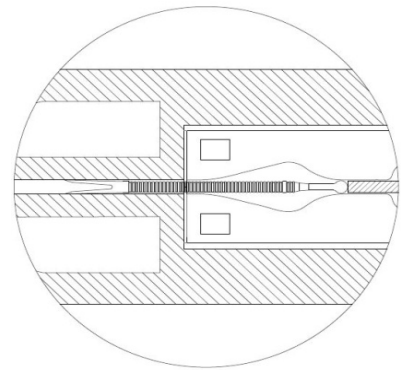
In the present research study, the cartridge chamber has been designed to effectively and uniformly crimp the "Y"-shaped end of the implant without causing any damage. The crimping process of the implant's "Y" shape end occurs in three distinct phases, as illustrated in Figure 06. Figure 06(A) represents the initial placement of the implant within the cavity. Figure 06(B) demonstrates the implant's "Y" shape end in a partially crimped state, highlighting the gradual crimping facilitated by the cavity towards a reduced crimping profile. Finally, Figure 06(C) portrays the implant in a fully crimped position as it approaches closer to the needle.



**Figure 6(A): Placement of Implant in the Cavity**

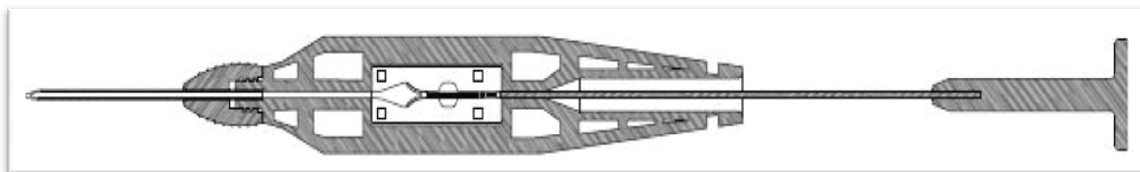


**Figure 6(B): Implant's Y-Shape end in Semi-Crimped Position**

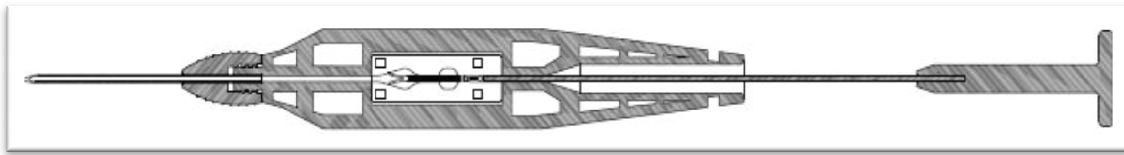


**Figure 6(C): Implant Fully Crimped**

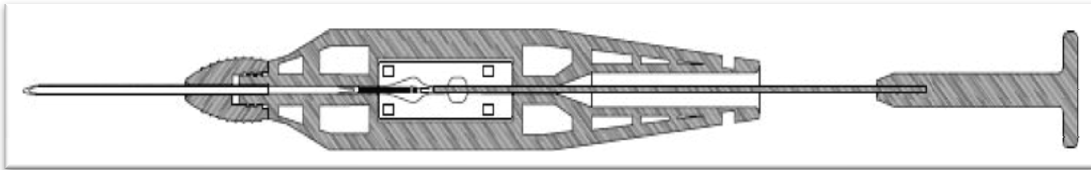
Pusher rod location during the crimping and travel processes is depicted in Fig.07 (A), (B), (C), and (D), respectively. To avoid damaging the implant, the pusher rod is softly pushed throughout the entire crimping and travelling procedure.



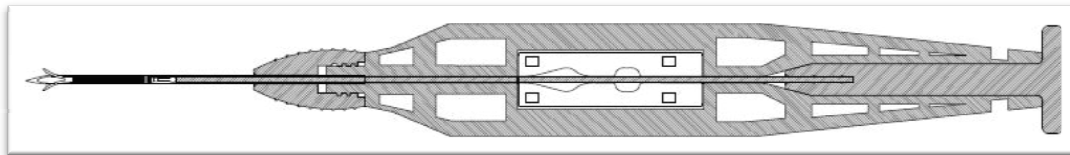
**Figure 7(A)**



**Figure 7(B)**



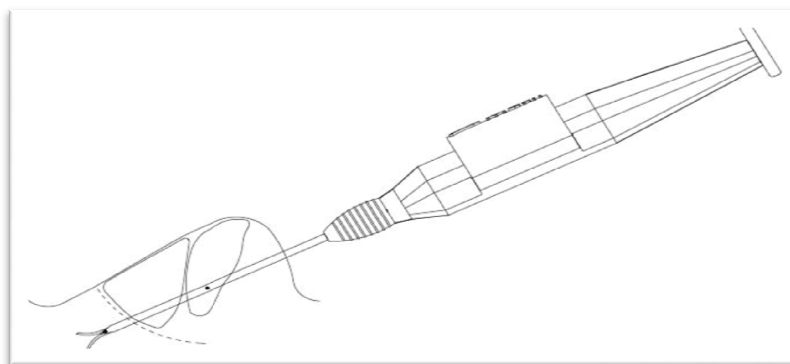
**Figure 7(C)**



**Figure 7(D)**

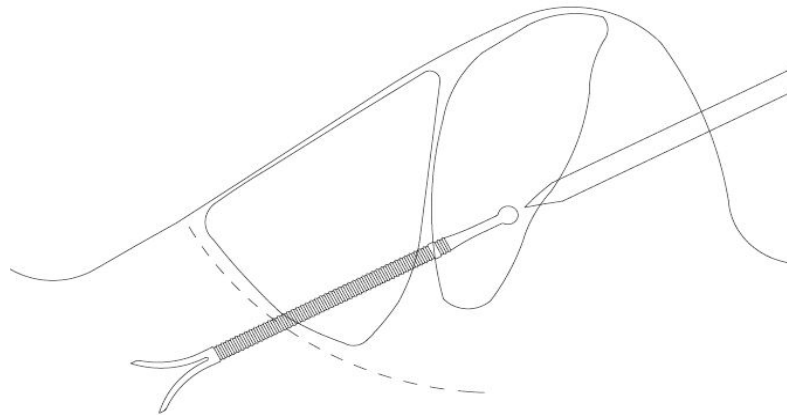
**Figure 7: Location of the Pusher Rod during the Crimping and Travelling Procedures.**

Using this technique, the delivery tool is prepared to deploy the bioresorbable nasal implant at the patient's treatment site. The implant is inserted into the treatment site by marking the desired location on the skin of the nose using a marking strip. This process aims to strengthen the cartilage and treat nasal valve collapse. Once the skin is marked, the surgeon uses a needle to create a tunnel or puncture based on the markings. The needle has sharp bevel ends that are crucial for effectively creating tunnels or punctures in the cartilage lining the nasal walls. When the needle reaches the intended spot, the implant is delivered by applying a final push using the pusher rod, as depicted in Figure 08. The implant in this innovative design features a "Y" shape at one end, which opens up to a maximum of 4mm during deployment. This "Y"-shaped end acts as an anchor, positioned between the skin and the nasal bone. The remaining section of the implant supports the upper and lower cartilage, thereby restoring the nose's structure.

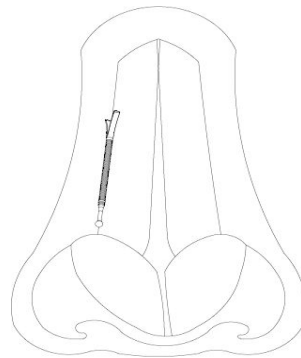


**Figure 8: Implant Delivery at the Target Site by the Last Push of the Pusher Rod.**

The delivery tool is retracted with utmost care, following the guidance shown in Figure 09(A), after the "Y"-shaped end of the implant has been successfully deployed. Upon the delivery of the nasal implant, the patient's breathing will be enhanced, leading to improved respiration. Furthermore, as depicted in Figure 09(B), the cartilage will receive enhanced support.



**Figure 9(A): Retraction of Delivery Tool after Implant Deployment.**



**Figure 9(B): Deployment of Nasal Implant at the Treatment Site.**

In cases of severe nasal valve collapse, it is feasible to implant multiple bioresorbable nasal devices. These implants are made from a bioresorbable material, which means they gradually degrade and disappear within approximately 16 to 24 months. The design of these implants aims to minimize the risk of inflammation for the patient and ensures that their aesthetic appearance would remain unaffected.

## **RESULT AND DISCUSSION**

The results of our study demonstrated the successful manual operation of the bioresorbable nasal implant's delivery system with meticulous care as shown in the fig.10. Our primary objective was to ensure the secure extraction of the y-shaped implant from the needle as shown in the fig.10(C), and we accomplished this task without any complications. This achievement significantly boosts our confidence in the effective functioning of the delivery system when it would be implanted in-vivo in the future, specifically when deploying the y-shaped nasal implant at the intended site.

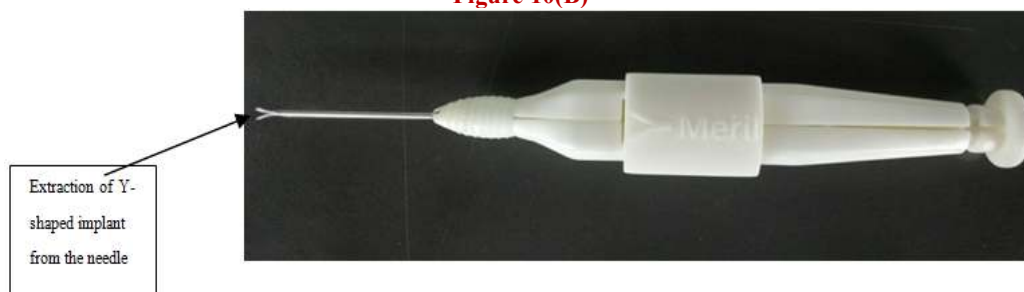


**Figure 10(A)**





**Figure 10(B)**



**Figure 10(C)**

**Figure 10: Operation of a Delivery System to Extract Y-Shaped Implant from the Needle.**

By employing utmost care and precision throughout the extraction process, we were able to validate the reliability and safety of the delivery system. This success establishes a strong foundation for the future utilization of the y-shaped nasal implant in clinical applications. Our findings indicated that the delivery system can be operated without compromising the integrity of the implant or causing any adverse effects.

The manual operation of the delivery system allowed us to closely monitor and control each step of the extraction process, ensuring a smooth and successful implant deployment. These results suggest that the delivery system would possess the necessary attributes to consistently deliver the y-shaped implant to the targeted nasal site during in vivo procedures.

Based on our comprehensive analysis, we confidently predict that the bioresorbable nasal implant's delivery system would undoubtedly function effectively and reliably, meeting the desired outcomes during future in vivo procedures. This achievement holds great promise for enhancing the success rates and overall performance of nasal implantation procedures when implemented in vivo for which we have initiated the process. It has the potential to advance the field of bioresorbable implants and their applications in clinical settings.

## **CONCLUSION**

In conclusion, the described delivery system represents a substantial leap forward in the field of nasal implantation. With its capability to enable effortless and precise positioning of the implant, offer support to the nasal cartilage, and mitigate potential risks and errors, it stands as a noteworthy reference for both preclinical and clinical studies. The system's innovative design, incorporating a needle with a sharp bevel and a protective coating, ensures smooth and safe insertion while preventing nasal wall collapse and airway blockage. Additionally, the cartridge configurations of the delivery tool reduce human handling errors during implant loading, enhancing accuracy and reliability. By providing significant



advancements in the delivery process, this system has the potential to enhance the efficiency and safety of nasal implantation procedures, ultimately benefiting patients and practitioners alike.

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