

## Endossage – Bridging a Pelvic Pain Therapy Gap



### Executive Summary

Historically, medical devices for the treatment of pelvic pain and conditions causing pelvic pain have been overlooked or underdeveloped by the biomedical community. Many doctors and therapists had limited options to recommend to patients seeking therapeutic relief beyond the setting of a clinical visit. As such, medical professionals have had to resort to using either adult novelty products designed primarily for sexual stimulation and not particularly suited to the problems facing a patient or to a limited variety of medical products which have had very limited focus.

Additionally, very little has been done to address the needs of clinicians and practices that experience workload issues and fatigue experienced by professionals created by the increasing population of pelvic pain patients seeking therapy. As such, some clinicians have expressed a need for a device that could be used in the clinical environment to address the issues of therapist fatigue, as well as a commonality of purpose between a clinical and patient use device. While nothing can substitute the direct physical interaction between practitioner and patient and the real-time tactile feedback associated therewith, a device that can augment and extend treatment time and options not possible with direct manipulation or other constraints has been sought after by some professionals.

### Introduction

As the population of individuals suffering from pelvic pain causing disorders becomes more familiar with the options available to alleviate their pain, the number of patients seeking physical therapy as a pain management or cure is steadily rising. While physical therapy is an excellent option for many pain sufferers, accessibility to continued long-term treatment proves to be a challenge to many individuals. Patients and medical professionals have expressed frustration with an inability to extend treatment beyond, or have been hampered by other constraints within, the clinical environment. Few medical device options have been offered as a solution to any of these challenges. Devices that are available are limited in scope of use and proper design for the specific tasks required. Furthermore, the devices currently available do not consider the issues of practitioner fatigue and workload or situations where a patient is averse to direct personal contact.



## The Un-Bridged Gaps

Pelvic pain physical therapy is one of the fastest growing sectors in the physical therapy field. Patients with acute and chronic pain are slowly beginning to learn that there are therapy options to alleviate pain of which they have not been aware. The reasons for taking a physical therapy route are numerous.

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- 1) Some patients may be recovering from surgical procedures where therapy can mitigate post-surgical pain or complications.
- 2) Other patients may have conditions where medication or surgical remedies may not be useful or have not worked to alleviate pain.
- 3) Still others may wish to take a generally less invasive approach to their pain issues that preclude traditional medications and surgery.

Whatever the reason, there is a rise demand for pelvic pain therapy and associated products designed to that end.

While there is a good deal of effort being dedicated to the education and training of new pelvic pain physical therapy specialists, little has been done to address the need for physical therapy medical devices for pelvic pain relief. None of the devices to date have taken a structured biomedical approach to address all of the areas and techniques used by physical therapists and incorporate a plurality of those options into a single modular system that can be used by a practitioner or a patient.

**Devices at the disposal of practitioners have fallen into one of the following categories:**

**Static Dilators  
Kegel Exercisers  
Trigger Point Myofascial Release  
Thermal Therapy  
Vibration  
Electro Stimulation**

While these devices all have their place and efficacy for particular indications, the area completely unrepresented is internal massage/manipulation therapy. None of the products on the market, to date, attempts to mimic or reproduce the motion provided by a physical therapist that administers internal massage and manipulation.

In addition, none of the devices on the market are designed as a modular multi-purpose system with the ability to be adapted and expanded to administer more than one of the effects of the other devices listed above. Sadly, the few devices on the market that do provide multiple effects are designed for the adult novelty market. Practitioners, for years, have had to resort to prescribing adult toys that are not specifically designed to address the clinical needs and were products merely approximating the requirements a true multifunction medical device should offer. Obtaining and possessing such adult novelty items could prove embarrassing and uncomfortable for certain segments of the population, leaving them with very little choice.



Finally, none of the current products available to the clinical community offer a multifunction device that is designed to seamlessly cross over from clinical use to at-home use by the patient. Extending therapy beyond the clinical setting is considered paramount to many clinicians to aid patients in pain relief on an ongoing basis.

## Solution Gaps

All of the devices and products currently available on the market provide relief in one fashion or another; however the products currently available provide no more than two of the desired therapeutic effects in a single solution. Furthermore, none of the products provide internal dynamic massage/manipulation effects. None of the products are modular. None of the products are designed to aid in clinician fatigue relief. Lastly, none of the products are designed for continuity of use from the clinical setting to the home self-help environment.

For example, the trigger point products currently available, while generally effective when properly used, have their short falls. Some patients complain that the material is too hard and unyielding. Others suggest that the size and shape doesn't quite work for certain individuals. This limited offering approach, while appropriate from a production and marketing perspective, simply doesn't work for a great number of patients. While certain products in this category can also have additional features such as thermal or vibration therapy, none are built on a modular platform that can provide more than two effects from one device.

Another example, static dilators, have been marketed for years. The technology is simplicity at its best and worst; an array of graduated tapered cylinders allowing the patient to progress through diameters as they become more tolerant. The deficiencies of this offering become apparent quite rapidly. Most products are hard and unyielding plastic, metal or other hard substance. The advance in graduated diameters are finite and the incremental change proves too much of a step for some patients. Again, these products provide a single effect solution with the occasional thermal or vibration effect added on some models.

- These devices do not address most of the advanced therapeutic concepts that have become prevalent since their inception.
- They are ill suited to trigger point release therapies.
- They do not adequately induce the blood flow and myofascial release associated with trigger point or internal massage/manipulation.
- They are primarily designed for patient home use; but they are ergonomically unfriendly and usefulness is therefore limited.

The pelvic therapy community requires a device that is modular and flexible enough in design to provide a variety of therapeutic effects in one product. The device should allow for multiple attachment options that a patient or professional may choose from that best suits the particular clinical indication. Those options should also be cross compatible between the clinical use product and the home use product. The product should be easy to use for the clinician requiring his or her own fatigue management, yet be ergonomic in design for home use so that patients may comfortably achieve the same effects of the device themselves that the professional can achieve in the clinical setting. Lastly the product should be designed in such a way that a single device may accept future attachments providing updated effects or customized attachments for special case users.



## Endossage - Bridging the Gaps

Endossage, designed and produced by GreMedix, has been specifically developed to offer a more comprehensive solution that bridges the gaps between the clinic and home therapy. It delivers therapeutic motions previously unavailable in a therapy or medical device. Endossage also provides the modular and scalable design that allows customized therapy for patients beyond the clinician's office.

Endossage is a complete therapy system for pelvic pain comprised of a base controller that accepts a variety of attachments. The base control units come in two models. One model is designed for use by the therapy professional in the clinical setting. The second model is designed for use by the patient in the privacy and comfort of their own home. Both models are designed to use three families of attachments that are completely interchangeable between the clinic and patient base controllers. The attachments consist of massage, trigger point, and dilation therapy. All of the families of attachments have a specially formulated soft prosthetic medical grade silicone covering and have the option of added vibration therapy.

The Endossage clinical model is a hand-held device designed for professional use when a therapist may not want or be able to provide direct personal contact. The primary motivation for the clinical model is to aid the therapist who experiences fatigue from the repetitive motion involved in administering internal massage techniques. In practices where many patients require massage or manipulation and the number of therapists trained to administer manipulation is limited, chronic fatigue has become an issue for some professionals. Aching hands need a break and Endossage for the clinician allows professionals to administer therapy to more patients, while giving their hands the rest they may desperately need. Furthermore, some patients are not comfortable with direct contact based on religious or other personal reasons. The clinical model allows a practitioner to administer some form of therapy while maintaining a physical distance a patient desires.

While nothing is a substitute for the direct contact and tactile feedback that a trained therapist can administer and interpret, the Endossage clinical model gives the therapist a tool for manipulation that was not previously available in the situations described.

Professionals have long sought a way for patients to administer self-therapy after treatment has concluded in the clinical environment or when a patient was unable to visit the therapist's office. The Endossage patient model is an ergonomically designed hand-held device developed for use in the privacy and comfort of a patient's home.

By virtue of its extended, flexible neck that connects the base control to the therapy attachments, Endossage is the first medical device that a patient can use in a relaxed and comfortable position. The flexible neck can be articulated in such a way that the patient can properly maintain pressure and position of the attachment without the need to tense pelvic or abdominal muscles that may interfere with the therapy being administered. This design also places the function controls in a position that the patient can easily see while using the device. Endossage for patient use accepts the same attachments used on the clinical model. Patients that experience Endossage in the clinic can therefore expect to

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have similar effects from a nearly identical device they can use at home. The clinician can help a patient chose the right attachment for their situation, train the patient in its use, and then send the patient home with the knowledge and comfort that they can now bridge the gap between clinical treatment and home therapy.

## Unique Design Considers Individual Needs of Patient

### Massaging Motion

Endossage's unique massaging motion family of attachments is designed to mimic the motions provided by internal massage therapy specialists. A reciprocating component that moves along the long axis of the penetrating attachment simulates the contact and pressure of a therapist's fingertip or fingertips massaging the particular area needing massage. The motion can be localized and speed varied to provide the optimal effect needed for that particular patient. The attachment comes in three standard diameters, each graduated so that the diameter of the moving element is the diameter of next larger attachment's minimal shaft diameter. This adds the ability to provide dynamic dilation therapy as well as massage therapy in the same component family. The moving element can also be customized if the profile diameter or shape needs to be adjusted for certain patients' needs. All of the attachments in this family can also be fitted with a very mild, low-G vibration if that would be deemed useful for a particular therapy. The vibration option is operated independently from the massage motion so that either affect can be used alone or in conjunction with the other.

### Dilation

The Endossage family of dilating attachments is designed to provide dynamic dilation therapy for those that need a uniform, gentle, and graduated dilation effect. Traditional dilators are simple hard material tapered cylinders that come in an array of successive diameters. While these are acceptable for some patients, some find that the jump in diameter from one size to the next is not tolerable. Others find that the materials offered are too hard and rigid for their comfort. The Endossage family of dilating attachments are designed to dilate and expand slowly, under the control of the patient. The device user starts with the smallest diameter of the attachment and then dilates it slowly to the desired size up to its maximum diameter by using the base control function buttons. This design allows for infinite incremental changes in diameter between minimum and maximum diameters of the attachment. Once the patient can tolerate the maximum diameter comfortably and consistently, the next larger diameter attachment can then be used if desired. The maximum diameter of each attachment is the minimum diameter of the next larger size. In this way, patients do not need to make an uncomfortable or intolerable jump in sizes and can now more gradually move through the course of therapy.

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The dilation motion is not in a simple circular pattern when viewed in cross-section. The expanding motion is designed as a smooth, over-all circular shape; however produces slightly more force in three directions -- 120 degrees apart. When dilated, this rounded triangular shape is designed to present



pressure on the musculature and connective structures surrounding the vaginal opening while avoiding direct pressure on the urethra. No traditional graduated dilators are designed with this in mind. The soft silicone cover of attachment further attempts to make the dilation therapy as comfortable as possible. All of the attachments in this family can also be fitted with a very mild, low-G vibration if that would be deemed useful for a particular therapy. The vibration option is operated independently from the dilation motion so that either affect can be used alone or in conjunction with the other.

### **Trigger Point Release**

The trigger point release family of attachments from Endossage represents a new approach to trigger point therapy devices. Trigger point release products have been, until now, more or less the same design for years. Trigger point release devices have been made of rigid materials such as tempered glass, Lucite, and other types of plastics. These materials, particularly the tempered glass products, have the ability to be warmed or cooled to provide a level of thermal therapy alongside the trigger point release being employed. This is a very desirable option for some. However, certain patients have been concerned with the use of glass objects. While completely safe when properly manufactured, the glass products still give some cause for concern. Still others simply feel that the rigid properties of the trigger point products are too unyielding and uncomfortable. Another complaint is the limited shape and size options offered in the trigger point release product spectrum. The Endossage family of trigger point release attachments is designed to provide an alternative to the deficiencies in materials, shape and size options that have caused concern for some. The Endossage trigger point attachments are available in a variety of diameters from which a patient or practitioner can choose to best fit the patient's need. The defining design feature of the Endossage trigger point attachments is that it is flexible and soft but can hold a particular shape and angle as defined by the user. The attachment is comprised of a rigid yet flexible center core with a bulbous rigid body -- with the end entirely enclosed in a specially formulated, multi-layered, medical-grade prosthetic silicone. The attachment is designed to feel more natural and closer to that of human finger than a rigid tool. The advantage over a human finger is that the diameter and length of reach can be greater than that of a finger as well as be bent and shaped in ways a human finger cannot be articulated. All of the attachments in this family can also be fitted with a very mild, low-G vibration if that might be deemed useful for a particular therapy.

### **Why You Need the Endossage Solution**

Depending on whether you are a professional or a patient, your motivation for obtaining the Endossage system will be different but with a similar goal in mind. The ultimate goal of any medical or physical therapy device is to cure or alleviate symptoms as quickly and safely as possible, and it needs to be easily accessible to those who need it.

Clinical professionals will find their needs fulfilled by Endossage in that they are able to attend to and help more patients when fatigue sets in and staff requirements are strained. Aiding more patients helps to expand the practice and provide relief for more individuals than would otherwise be possible. Endossage is another tool in the toolbox of therapists dealing with pelvic pain and pelvic disorders that

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expands the reach of this specialized area of therapy. Furthermore, Endossage allows the professional the ability to administer therapy to a segment of the population that was otherwise, quite literally, untouchable. Patients that had religious or other personal objections to an individual administering direct contact therapy now have a viable path for obtaining therapy from a trained professional. There is a large, untapped, part of the pelvic disorder population that has been found to be in this category, particularly in the major metropolitan areas where ethnic diversity and immigrants are concentrated.

## Modular Design Increases Your Return on Investment

The modular design of the Endossage system also allows the clinician the ability to use one device for multiple patients with different therapy needs. The interchangeable attachments allow the practice to maintain hygienic protocols by using a washable reusable attachment assigned to each patient. This system allows one base unit to provide multiple therapies to multiple patients, decreasing cost of ownership by allowing the patient to purchase the attachment for their needs. The practice can supply the attachments to the patient for a cost or as a treatment option. This also gives the practice the flexibility to supply multiple effects with one device, which is not currently the case with other products of this nature.

## The Freedom to Go Beyond Insurance Limitations

Most insurance will reimburse a limited number of sessions when it comes to the payment of physical therapy. Patients and clinical professionals find that the number of sessions covered by insurance often falls short of the time needed to complete therapy or a patient may simply require more therapy than is typically expected. This causes one of the gaps mentioned in pelvic pain therapy. Endossage for the patient bridges that gap in several ways.

- 1) Endossage can extend therapy beyond the time allowed by insurance indefinitely and for a predictable cost.
- 2) Endossage gives patients that do not have insurance an alternative to expensive clinical visits by providing a home self-help therapy option.
- 3) Endossage can also be employed as an intersession home therapy aid when more therapy is required between clinical visits.
- 4) The cost of an Endossage patient model is easily justified when the expense of travel, co-payments, and time are tallied. For some, even if cost of clinical visits were not an issue, convenience and or personal concerns preclude a patient's ability to seek out therapy in a clinical setting.

For patients requiring multiple types of therapy such as massage and trigger point, the Endossage modular design further extends the return on investment by the ability to combine multiple effects in one device. A single device is now scalable for the patient by selecting the appropriate group of attachments that best suit their needs. The patient can customize the therapy further by adding attachments as their condition changes or improves as in the case of dilation therapy. Patients now have a medical therapy device at their disposal that is cost effective relative to the expense of travel, inconvenience, and short falls in insurance coverage. Endossage is a true therapy device that patients can purchase and customize for a reasonable cost rather than the less than optimal and long term more costly options of single solution items or ill-suited adult novelty devices.



## The Endossage Bridge - In Short

Endossage is a cost-effective device that bridges the gaps left by other therapy products and addresses short falls in a patient's ability to obtain direct professional aid. Endossage also provides professionals a new tool by extending their availability to patients by relieving clinician fatigue. In addition, Endossage can provide an option for patients who, for some reason, cannot be treated with direct physical contact.

Endossage further bridges the gaps by presenting an ergonomic, modular, scalable, and customizable therapy device that can be configured and adapted to provide a range of therapeutic effects from a single base device.

Endossage is a product without which some may never experience continued ongoing therapy or relief.

## Bridge Those Gaps Now

Medical professionals and therapists can obtain the clinical model of Endossage in several ways.

For a limited time, qualifying practices can try Endossage on a 60-day risk-free evaluation. During the evaluation GreMedix, makers of Endossage, asks for clinical feedback on patient response and data for the purposes of improving and gathering more information on use patterns and efficacy.

At the end of the 60-day evaluation, the practice has the option of returning the device with the data obtained or can continue using the device and supply one to all other clinicians in your practice as follows:

### Subscription Option

Professionals can obtain Endossage by direct purchase on our website or by committing to a 1 year attachment subscription. The one-year subscription is a \$100 minimum monthly charge and supplies 2 attachments of choice each month. Additional attachments can be purchase at added cost and volume discounts are available. At the end of the 12-month subscription the Endossage clinical base model is the practitioner's to keep. Early termination penalties of the subscription apply and subscription qualification is based on credit approval and deposit. Go to [www.endossage.com](http://www.endossage.com) or contact us at [Info@endossage.com](mailto:Info@endossage.com) for details.

### Installment & Rental Options

Patients can obtain Endossage by purchasing on the website or installment payments with qualified financing. Patients may also rent Endossage units on a monthly basis and requires the purchase of at least one attachment of choice. Credit card deposit for the product, first month's rent and purchase of the attachment are due at time of rental.

Special discounts and promotional pricing are available from time to time. Check [www.endossage.com](http://www.endossage.com) for the most current pricing and promotions.

