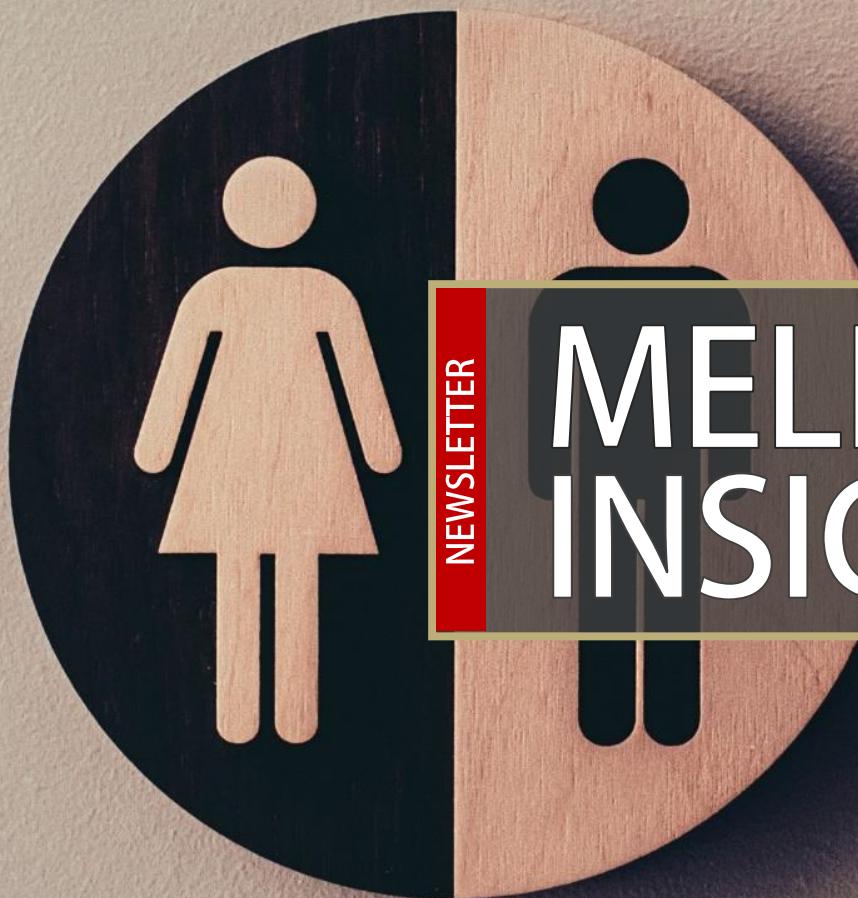


JUNE 2020  
[www.meliorcm.com](http://www.meliorcm.com)



# MELIOR INSIGHTS

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The revolutionary device that can give women back control of their life

*This newsletter is for education purposes only and addresses past events. This newsletter is not an offer nor an invitation to subscribe.*



## Introduction to Melior Capital Management

# MELIOR

/me'ljor/  
(from Latin)

BETTER, SOUNDER, SUPERIOR

Melior Capital Management is a Swiss domiciled company introducer and advisory firm focused exclusively on the global life science sector.

We specialise in finding funding for medtech, biotech and pharmaceutical companies by applying institutional quality service and process to raise capital.

Our investment approach is to find qualified innovative projects, with proven management teams, promising data, robust IP, strong corporate governance and a likely opportunity for significant commercial upside in a three to five-year horizon.

In the current environment, many existing companies seeking capital for medical trials have encountered a diminishing supply of funding from governments, private equity firms, investment banks and research foundations in favour of start-ups. At Melior, we combine the global reputation of our scientific, management and advisory members to select best in class investment opportunities with credible upside potential.

Our value proposition is attributable to our world class team and their proven track record in the life-science sector, plus the strong emphasis that we place upon due diligence and first-hand experience. Our goal is to offer attractive

and diverse investments to both high net worth private clients and larger corporates through their professional advisers. For our business to be truly successful, we consider the needs of all parties, including our investees, investors and professional advisers at introduction and throughout the life of the investment. Our financial success depends on funds raised and the financial return of our investees as we share a common goal.

In this edition of our newsletter – Melior Insights, we review urinary incontinence issues, particularly focusing on stress urinary incontinence (SUI) and presenting to our readership an amazing device that is shifting the paradigms of SUI.

Melior does not accept enquiries from members of the general public, but we welcome enquiries from professional intermediaries.

*Melior Capital Management*

MELIOR CAPITAL MANAGEMENT



## AN UNSPOKEN FEMALE HEALTH CARE CRISIS

A critical issue affecting millions, yet often ignored



**85%** of people with UI  
are women



**50%** of women suffer from UI  
at some point in their lives



**423m** of the population have UI  
(**8.7%** of the global population) –  
2006



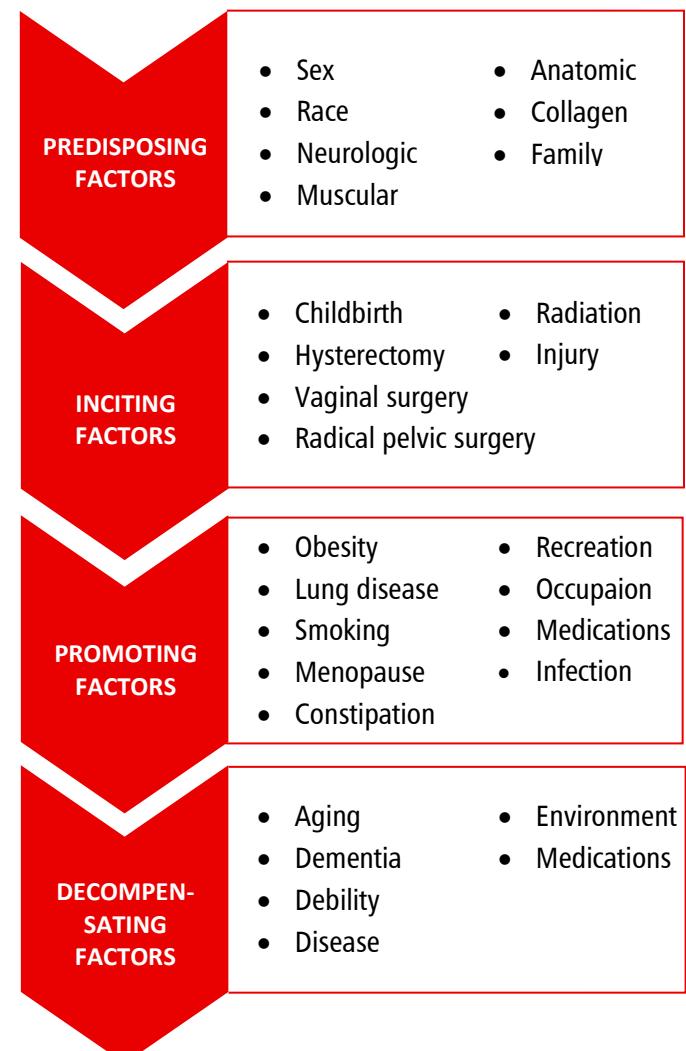
**UI market:**  
**\$10.2bn** in 2016, **\$15.5bn** by 2024

**U**rinary incontinence (UI) is a topic that is seldom mentioned, yet it affects millions of people and creates significant physical, emotional and mental health costs, as well as resulting in direct and indirect economic costs. UI is the involuntary leakage of urine; loss of control of urination has a considerable negative impact for those affected.

UI is a condition that affects both men and women, although the number of women affected is significantly higher at 85% of people with UI. In fact, it is estimated that 50% of women suffer from UI at some point in their lives. These conditions are caused by a number of factors which are outlined in the figure on the right.

A 2006 study estimated that the global prevalence of UI is 8.7% or about 423 million people, which is larger than the current US population and, if it was a country, it would be the third largest after China and India in terms of population. The incontinence market was estimated at \$10.2 billion in 2016 and is forecasted to reach \$15.5 billion by 2024.

With growth of the global population and increasing life expectancies, it is anticipated that the UI market will





continue to expand, with people looking for solutions to maintain and improve their quality of life in their older age.

In the subsequent table, we outline the six existing forms of UI and then proceed to show the historic and current split in some of the most important markets.

#### Stress incontinence

SI occurs when any physical exertion increases abdominal pressure, resulting in pressure on the bladder and urine leaks, is called stress incontinence. This condition occurs when the pelvic floor muscles have been weakened, affecting men after pelvic fractures, prostate surgeries or damaged urinary sphincter; and women, particularly as they age.

#### Overflow incontinence

OI occurs when the bladder is not completely emptied, which may result in urine leakage, with or without feeling the need to go. This is most often caused by blockages of the urine flow out of the bladder, like the cases of prostate enlargement, partially closing the urethra; and due to the underactivity of the bladder muscle, which results in overfilled bladder and leakages. This incontinence is more predominant among men, suffering from prostate issues, tumors, scar tissues or bladder stones. In women, it is usually caused by prolapse of uterus or bladder, resulting in obstruction of normal urine flow through urethra or nerve damages (from injuries, childbirth, diseases or past surgeries) affecting the normal contraction.

#### Urge incontinence

UI occurs when a strong urge to urinate is felt, even when the bladder is not full. It is often that the root cause of urge incontinence is not diagnosable, with the condition is more predominant among the aging population. Myofascial pelvic pain syndrome, infections of the urinary tract, bladder or prostate, diabetes and neurological diseases (ex. multiple sclerosis and Parkinson's disease) can lead to overactive bladder. Stroke causes UI, with 40% to 60% of hospitalised patients after a stroke having this form of incontinence, by the time they are discharged the rate decreases to 25% and one year later to 15%.

#### Functional incontinence

FI occurs when the incontinence is not caused by problems of the urinary tract, but rather by other illnesses or disabilities that prevent the person from making it to the toilet in time. It can be caused by physical (e.g. severe arthritis) or mental impairment (e.g. dementia), which either make the person unaware, unconcerned or unable to properly execute this physiological need.

#### Mixed incontinence

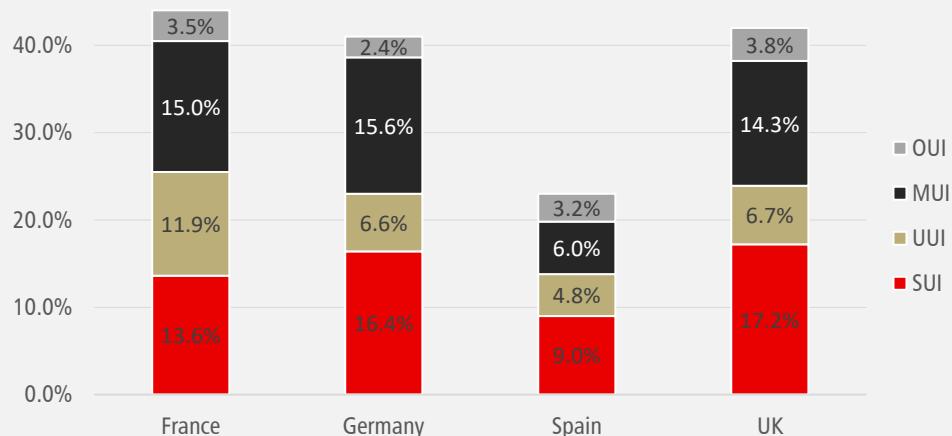
MI occurs when a person suffers from two or more concurrent incontinences, called mixed incontinence. Typically, it is the combination of Urge and Stress incontinences, that affect both men and women, especially frail older people.

#### Reflex incontinence

RI occurs when the contractions of the bladder muscle happens uncontrollable, resulting in urine leaks. It is caused by the damage of the nerves that normally warn the brain that the bladder is filling. This condition usually appears in people with serious neurological impairment from multiple sclerosis, spinal cord injury, other injuries, or damage from surgery or radiation treatment



A 2004 study<sup>1</sup> looked at the occurrence of various UI conditions for women older than eighteen. The estimates of occurrence of UI is estimated at staggering levels, with 44% diagnosed in France, 41% in Germany, 23% in Spain and 42% in the UK:

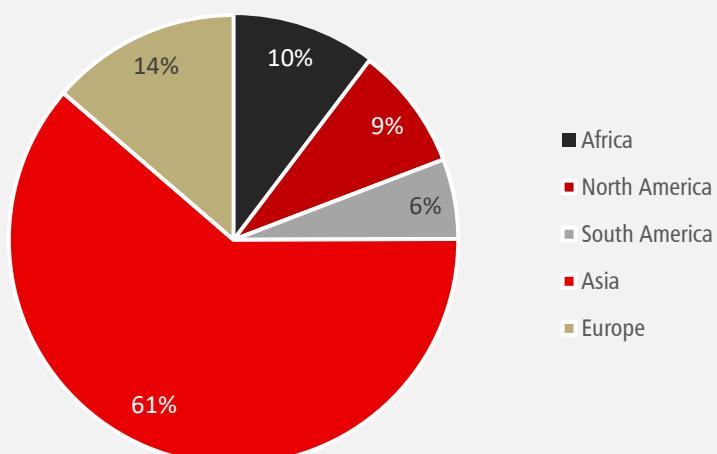


A 2009 study, focusing on women older than forty indicated even higher numbers, with 67% of this population suffering in the US, 69% in the UK and 67.1% in Sweden:



The global estimates of individuals with UI grouped by year and region (in millions), and the global distribution in 2018 reveals staggering data:

Region	2008	2013	2018
Africa	33	38	43
North America	32	34	37
South America	20	22	24
Asia	206	231	256
Europe	54	56	57
<b>World</b>	<b>346</b>	<b>383</b>	<b>420</b>

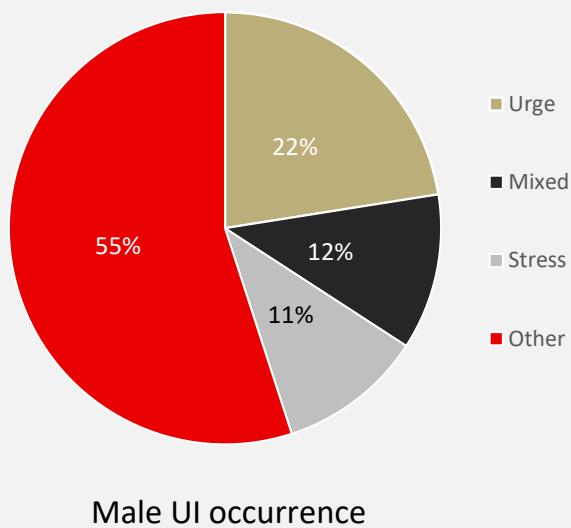


<sup>1</sup> SUI - Stress urinary incontinence, UUI - Urge urinary incontinence, MUI - Mixed urinary incontinence, OUI - Other urinary incontinence

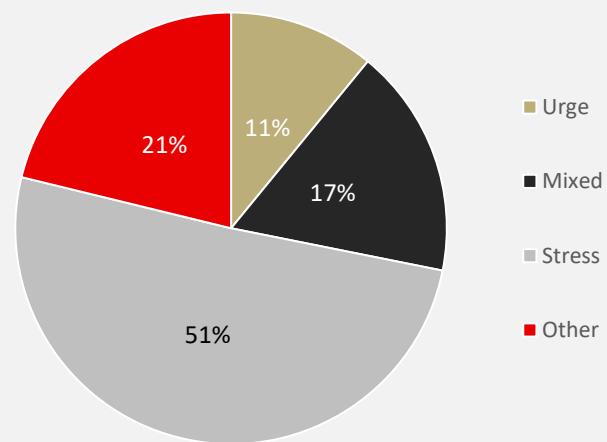


The estimated number of individuals with UI by year and sex (in millions) reveals an increase in prevalence:

Urinary incontinence	Male			Female		
	2008	2013	2018	2008	2013	2018
Urge	22	25	27	27	30	33
Mixed	11	12	14	43	47	52
Stress	10	12	13	127	140	153
Other	55	61	66	53	58	64
<b>Total</b>	<b>98</b>	<b>109</b>	<b>120</b>	<b>250</b>	<b>275</b>	<b>301</b>



Male UI occurrence



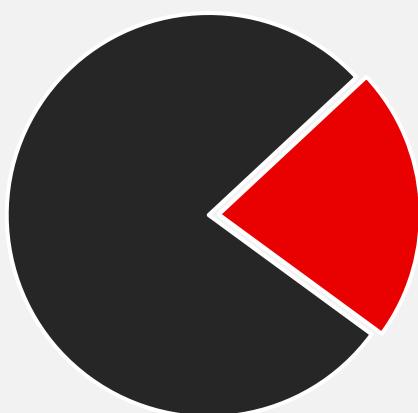
Female UI occurrence

SUI is the dominating form of urinary incontinence, particularly among women. A more detailed review of this condition will be outlined in the next article of this newsletter.

**Sources:** Harvard Medical School, Mayo Clinic, National Center for Biotechnology Information, Epidemiology of Incontinence and the Melior Insights Team

## STRESS URINARY INCONTINENCE (SUI)

A debilitating condition limiting the lives of millions of women



78% of these have SUI

60% of these women  
avoid athletic activities

80% are more likely to  
develop depression

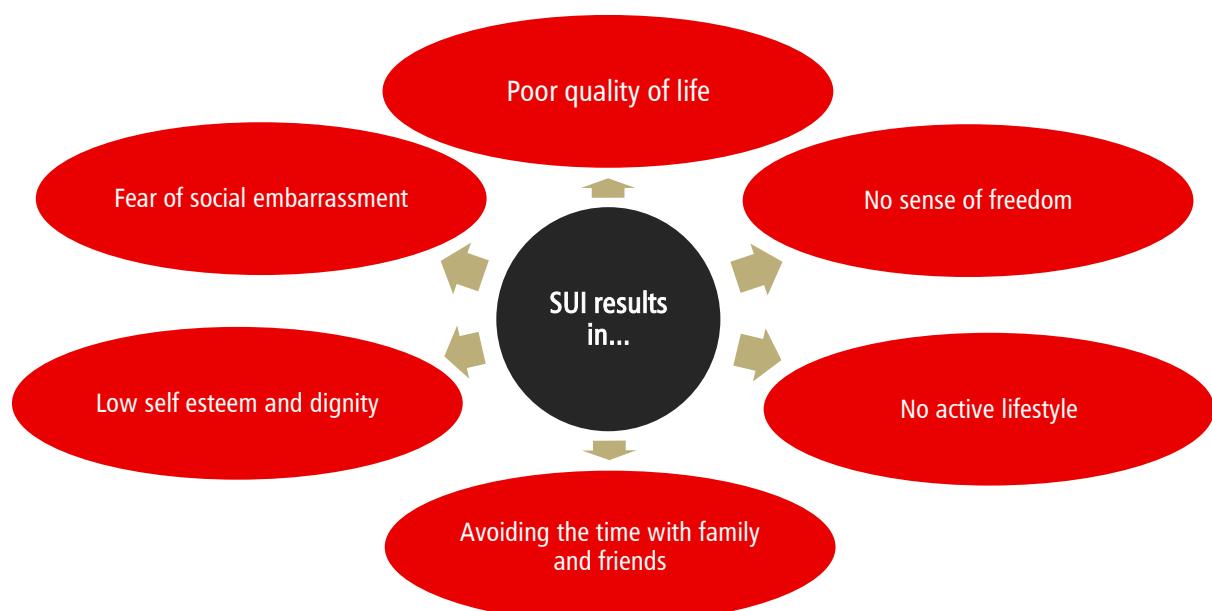
**29% of women aged 30 to 60 have UI**

### SUI HAPPENS WHEN:

- PHYSICAL MOVEMENT STRESSES THE BLADDER
- PELVIC MUSCLES WEAKEN
- VALVE-LIKE MUSCLES FAIL

### SUI TRIGGERS:

- |            |                 |
|------------|-----------------|
| • COUGHING | • RUNNING       |
| • LAUGHING | • JUMPING       |
| • SNEEZING | • HEAVY LIFTING |
| • EXERCISE | • SEX           |





**A**s outlined on the previous page, Stress Urinary Incontinence (SUI), also called Light Bladder Leaks (LBL) happens when physical movement or activity puts pressure (stress) on the bladder, causing urine leakage. This is the result of weakening of the muscles and other tissues that support the urethra (pelvic floor muscles) and the muscles that control the release of urine (urinary sphincter). The bladder expands as it fills with urine. Normally, valve-like muscles in the urethra, the short tube that carries urine out of the body, stay closed as the bladder expands, preventing unintended urine leakage. But when those muscles weaken, anything that exerts force on the abdominal and pelvic muscles, like sneezing, bending over, lifting or laughing, can put pressure on the bladder and cause urine leakage. The name of "stress" incontinence is not related to psychological stress, although this condition often results in severe mental distress; the NCBI reports that women with SUI are 80% more likely to develop depression.

It is often the case that women affected by SUI, feel embarrassed by their condition and opt to self-isolate or are limited in their work and social life. In addition, physical and leisure activities are avoided; sometimes, those affected will undergo severe dehydration to prevent UI – all of these factors significantly affect health and overall well-being. In the US, 29% of women between the ages of 30 to 60 report that they have UI, with 78% having SUI and 60% of these women choosing to avoid athletic activities due to fear of leakage. Triggers of episodes of urine leakage can be quite trivial yet can have a severe impact on common daily activities.

Overall, SUI affects quality of life, restricting social activities, and leakage episodes can occur at inopportune times. At present there is no drug therapy available to completely eradicate this problem. A number of solutions have been developed; however, these solutions create a number of collateral issues, like lower quality of life, risks associated with invasiveness and environmental impact.

## UI Management Strategies

The treatment strategy for UI depends on several factors, such as the patient's age, general health and their lifestyle. The National Association for Continence divides potential solutions into four groups:

### Behavioural Modifications

- Pelvic muscle exercises
- Weight loss
- Biofeedback
- Pelvic floor stimulation

### Products

- Absorbent pads/briefs
- Pessaries

### Minimally invasive therapies

- Injection of bulking agents and Botox
- Radiofrequency therapy
- Sacral nerve stimulation

### Surgeries

- Mid-urethral sling surgery
- Traditional sling surgery



## Behavioural Modifications

Pelvic floor muscle exercises, also called Kegels, are exercises that tighten and relax the muscles that are interwoven between the vagina, urethra and rectum. Some women may benefit from these exercises to reduce leakages. However, these exercises must be performed correctly or there is no benefit. There are multiple tools on the market to attempt to support this training, but they require commitment, time and can take weeks to months before any benefits are seen. Even once benefits are seen, it requires continuous maintenance with life-long pelvic floor exercises. In addition, some of these support tools can cost up to several hundreds of dollars and still only have modest results. A reduction in symptoms of UI can also be achieved with weight loss which decreases pressure on the bladder. Overall, changes in behaviour including weight loss, pelvic floor muscle exercises, biofeedback (a non-drug treatment in which patients learn to control bodily processes that are normally involuntary, such as muscle tension, blood pressure, or heart rate) and pelvic floor stimulation can help improve muscle tone to better manage SUI.

## Products

Disposable pads, liners or briefs are often used to absorb and mask occasional leaks resulting from laughing, sneezing or physical activity. These products are easily accessible in stores alongside sanitary napkins although, they can be quite pricey considering their one-time use, with prices ranging from \$7.99 to \$35, depending on the type of material, brand and package quantity. It is recommended that these products are changed several times a day to prevent infections, skin irritation and odour, resulting in yearly costs ranging from \$200 to \$850 with the associated subsequent environmental burden.

An alternative approach is the use of pessaries which are devices that fit into the vagina and provide support to tissues displaced by pelvic organ prolapse (POP), a disorder in which one or more of the pelvic organs drops from their normal position. POP can develop after childbirth, surgery

or trauma causing damage to the pelvic floor and surrounding tissues. There are many different sizes and purposes for pessaries although they need to be fitted and managed by a doctor and often lead to lifestyle alterations, such as abstinence from intercourse. Pessaries may be covered by insurance in some cases, but typically cost several hundreds of dollars.



Different types of pessaries.

## Minimally invasive therapies

The injection of bulking agents into tissue around the urethra, helps to keep the urethra closed. Generally, this procedure is much less effective than more-invasive treatments, such as surgery, and must be conducted regularly to be effective. Botox (botulinum toxin type A) can also be injected into the bladder muscle, to help those with an overactive bladder. This solution is usually attempted only after other first line medications have been unsuccessful. Alternatively, radiofrequency therapy is a procedure that leads to the heating of tissue in the lower urinary tract. When it heals, it is usually firmer, often resulting in better urinary control. Another minimally invasive therapy is stimulation of the sacral nerve by an implant placed under the skin of the buttock. A wire connects it to the nerve that runs from the spinal cord to the bladder. The wire emits an electrical pulse that stimulates the nerve, improving bladder control.



## Surgery

There are two kinds of surgery that can be performed for women who are experiencing leaks:

- 1) Mid-urethral sling surgery: A thin strip of mesh is used to make the sling which is surgically placed under the urethra.
- 2) Traditional sling surgery: A strip of tissue from the stomach or thigh (or from a donor) is taken to make the sling. With two incisions in the vagina and abdomen, the sling enters through the cut in the stomach and is stitched to the inside of the stomach wall.

While these procedures have become common and have helped women prevent leaks, there is a significant financial aspect to consider. The procedure can cost \$13,000 or more depending on the type of procedure that is conducted. Surgery also entails follow-up costs and doctor's appointments that make it unattractive to many women: Prescriptions for drugs to manage pain after

surgery, ointments to ensure that incisions don't get infected, follow-up appointments with healthcare professionals after surgery to make sure everything is properly managed, all contribute to the overall costs of this procedure assuming that the surgery and recovery go well. The financial impact can worsen if there are complications that lead to more medical costs and this procedure has recently come under scrutiny with debate surrounding the risk/reward and true overall satisfaction after surgery. Indeed, the independent medicines and medical devices safety review commissioned by the UK government, published in July this year, stated that women adversely affected by vaginal meshes were due an immediate and fulsome apology for the pain and suffering they have experienced due to mesh implants, and should have access to a redress mechanism and a cost-of-care system to meet the financial requirements of additional needs caused by avoidable harm due to vaginal mesh.

Surgery today is in question due to its cost-benefit balance, it presents heightened risk for complications and at times is not even successful from the first run.

## SUI Consequences

SUI is a condition that is not easy to deal with and is associated with a number of repercussions that may severely affect the wellbeing of those affected:

Emotional distress	Mixed urinary incontinence	Skin rash or irritation
Repeated episodes of SUI severely intrude on daily activities, often creating embarrassment and distress, disrupting work, social activities, relationships and even sex life. This can result in depression and other mental health issues.	SUI often leads to an overactive bladder that can cause an urgent need to urinate, further aggravating the situation of the affected person.	Skin that is constantly in contact with urine may get irritated or sore and can break down. This happens with severe incontinence and can result in dermatological issues.

Sources: *Climacteric, Mayo Clinic, National Association for Continence and Melior Insights Team*



## IS THERE A BETTER WAY TO MANAGE SUI?

The revolutionary device that can give women back control of their life

As previously described, UI, SUI in particular, is a serious condition affecting the lifestyle of millions of people worldwide, with 18 million affected in the US alone (15 million women). SUI also causes significant financial impact through, for example, increased spending on household laundry which is estimated at \$600 yearly, taking into

account the cost of water, electricity and detergent, but ignoring the increased spend on clothes not to mention the environmental impact. There are currently no drug therapies to deal with SUI and a summary of the most popular options available for the control of SUI as described above, are shown below:

	Physical Therapy	Pads	Pessaries	Surgeries
Pros	<ul style="list-style-type: none"><li>• Does not require a prescription</li><li>• Relatively easy to do</li><li>• Equipment is relatively easy to find</li></ul>	<ul style="list-style-type: none"><li>• Do not require prescription</li><li>• Easy to find (pharmacies, shops and online)</li><li>• Easy to use</li></ul>	<ul style="list-style-type: none"><li>• Efficient in preventing urinary incontinence</li><li>• Sometimes covered by insurance</li></ul>	<ul style="list-style-type: none"><li>• Typically, are quite efficient</li></ul>
Cons	<ul style="list-style-type: none"><li>• Requires serious commitment and time for consistent results</li><li>• Not always effective</li><li>• The equipment may be expensive</li></ul>	<ul style="list-style-type: none"><li>• Is a one-time product</li><li>• Might require multiple pads per day</li><li>• Could result in skin irritation, infections and odour</li><li>• Significant environmental impact</li></ul>	<ul style="list-style-type: none"><li>• Most require a doctor's prescription, installation and management</li><li>• results in a number of limits to lifestyle (incl. intercourse)</li></ul>	<ul style="list-style-type: none"><li>• Some procedures have been deemed dangerous and forbidden</li><li>• Costly</li><li>• Chance of failure</li></ul>
Costs	-	\$200 to \$850 (yearly)	Several hundreds of dollars	\$13,000 + post operation expenses



Absorbent pads have long been the predominant measure taken by women with SUI, with the US market alone estimated at \$2.2 billion for all absorbent products (menstruation and incontinence). However, as mentioned above, this measure often creates secondary issues, for example, the NCBI estimates that folliculitis and dermatitis are 77% more likely to occur when treating SUI with pads, due to urine contact with the skin.

Surgeries seem an attractive option at first, but they are very costly, with NCBI estimating that the cost prior to surgery for women with SUI is \$900/year.

## A Paradigm Shifting Pessary

We feature an FDA-cleared product designed to safely and comfortably fit the female anatomy and able to be worn for up to twelve hours a day to ensure all-day protection. Moreover, the product is reusable, thus reducing waste and generating significant savings, while being easy to insert, remove, clean and store. The product is already available OTC at retailers in US box stores and on-line wherever sanitary products are found. Most importantly, this product allows women to return to their normal life.

PROS	CONS	COSTS
<ul style="list-style-type: none"> <li>• No prescription is required</li> <li>• Affordable and economical</li> <li>• Reusable and environmentally friendly</li> <li>• Easy to use and store</li> <li>• FDA approved</li> </ul>	<ul style="list-style-type: none"> <li>• Limited geographic distribution</li> <li>• Relatively low level of production</li> <li>• No international approval yet</li> </ul>	\$34.99 (monthly)

However, significant costs continue after the operation of \$150/year and more, and this assumes a successful surgery.

Considering all of the caveats of existing treatment options for UI, the optimal solution lies in the medical device niche, which was estimated to grow to \$3.6 billion by 2023 for global urinary incontinence devices, at a CAGR of 11.6%. In particular, the US over the counter (OTC) vaginal pessary market is estimated at over \$75 million. Indeed, a promising device was developed several years ago that was set to resolve the SUI issue, but it failed due to it being uncomfortable on use and removal. In fact, the usage of pessaries and other instruments serving the same purpose date back to ancient Greece, when Hippocrates mentioned the use of half a pomegranate in the vaginal opening to support prolapsed organs! Later, similar tools were made by Romans and other civilizations, but of bronze and silver. This market gap continues to be a huge opportunity and is set to be conquered by an exceptional product that is presented in the subsequent sections of this newsletter.

## The OVALA Project Team

It is no secret that the most important element of any company, whether that is an IT, Fintech or life science business, is team experience. The OVALA core team has been in the Medical Device Industry for over forty years, delivering over \$300 million in value to investors, including projects acquired by Shire and Medtronic. Their latest project, sold in July 2019, brought an OTC device to market that facilitated conception at-home for women having difficulty getting pregnant. The management team is solely devoted to this device without other distractions.

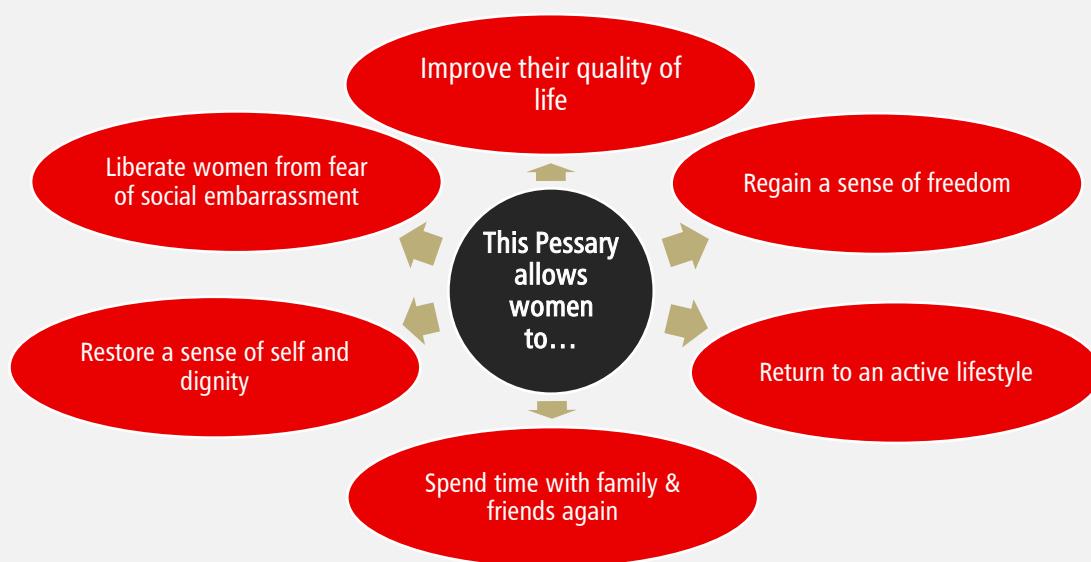
## Project Motivation

While the team was developing the conception device, they came across the issue of SUI and realised how significant a problem it was for so many women. The team then embarked on a parallel journey to find a reliable solution for stress incontinence. The first step was to



research and understand the current qualified global understanding of the disease state. By working with highly experienced urogynecologists and thought leaders in this field, a solution became apparent – a simple, mechanical and easy to use device that would not only manage urine loss, but stop it completely.

The second criteria the team chose to include was minimisation of the environmental footprint. Overall, the mission of the team was to develop a device that would empower women to reclaim their lives:



The optimal solution was found to be a mechanical pessary device to support the natural tissue to stabilize the urethra. These have been used for many years by physicians and are custom-fit for each individual patient being left in-place for extended periods of time with periodical management by a doctor.

However, a significant limitation is the need for abstinence from intercourse. Therefore, the team chose to take a different approach, focusing on the intended function of the organs rather than their deteriorated form. The team defined the following list of performance requirement criteria for their prototypes:

#### Delivery

Be Deliverable to the correct location by the end user themselves

#### Retention

Maintain the location no matter what the female vaginal tract size is

#### Support

Provide support to the urethra to prevent urinary leakage

#### Removal

Easy self-removal and maintenance

#### Comfort

During wear, placement and removal

#### Health

Maintain a healthy vaginal tract



## The OVALA Device

After designing, researching and developing many shapes, the OVALA team identified and tested the perfect shape which they have patented Worldwide.

Since vaginal tracts have various shapes, sizes and unique anatomical features, the unique OVALA design is able to overcome the issue of retention. Most other pessaries work by filling the vaginal tract circumferentially, which results in a requirement for multiple shapes and sizes to be available on the market, to fit or be retained within the vaginal tract, balancing performance with comfort. This is not ideal and a one size fits all product such as the OVALA will be more successful on a number of levels.



*The unique dual ring design*

As such, the team took an extra step and researched a shape that would accommodate sitting, standing and moving and in this process discovered that all women have a natural shelf intra-vaginally that is created while standing. The dual ring design, was designed to fit this natural shelf, resulting in a design innovation, the OVALA which retains its position.

Once the size and shape of the pessary had been defined, the design of the 'taper tip' or the working end of the device was investigated and an optimal shape designed, that also provides extra support during physical activities.

The next step was to identify the best delivery system. After several iterations, a tampon-like delivery tool was developed and proved to be easy to use. The last development stage was to find a safe way to remove the device. This was achieved with a simple cotton string - one

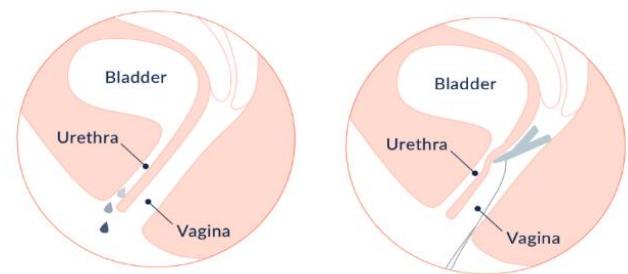
objective that was followed during the whole developmental process was to use as many recyclable materials as possible to reduce the environmental footprint, replacing pads.



*The delivery system*

The next step was to conduct clinical studies and obtain FDA clearance. These studies were conducted at five highly respected US hospitals, yielding the desired results. The device was proven to have a clinical impact on SUI by three critical criteria:

- Reduced leakage episodes
- Reduced leakage volumes
- Significant Improvement in Quality of Life



*The effects of the applied device*

## Future Plans

The team received FDA clearance and introduced the product to the US market in the summer of 2019. Validation, manufacturing, production and its scale-up were performed in parallel, so that entry into the market

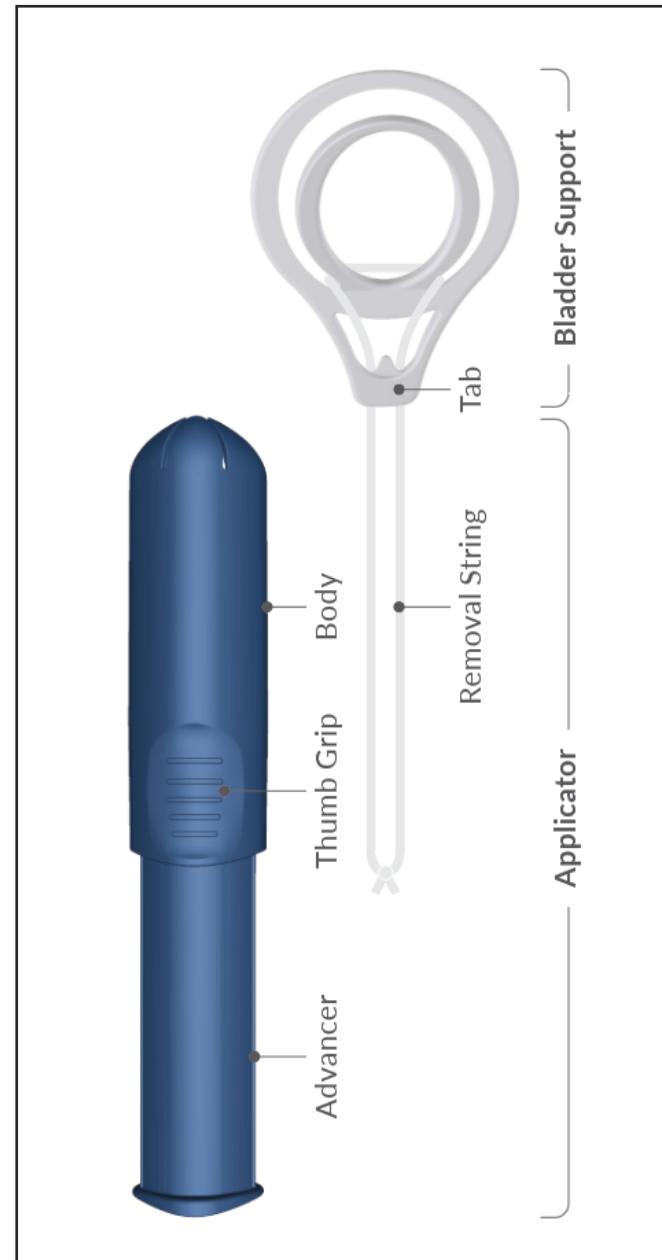


could be done in a most timely and efficient manner. The team identified a US manufacturing expert, which was able to establish production for a very reasonable cost, with margins over 70% for the team from the start, all while allowing the distribution partners to still have margins of over 40%.

The project has already arranged partnerships with two of the largest US distributors, but the team understands how important it is to implement a comprehensive marketing strategy in a timely fashion. The company is now raising funds to execute their full marketing plan within the US and to eventually expand into the EU, Middle East and other regions in 2021-2022. Significant efforts are already underway to help educate healthcare professionals within the US and Canada and to distribute the product to them. OVALA is now sold on Amazon and has quickly become one of the category leaders in online sales, achieving \$0.5 million in 2019 alone. The product is already patented in the US and other countries underpinning the marketing strategy.

OVALA offers a sustainable solution for millions of women suffering from SUI. All they need to do is to purchase this device using a different cotton string on each occasion, while the rest of the device is recyclable, resulting at an approximate daily cost of \$1.

This project represents a viable, efficacious, affordable, easy to use and environmentally friendly solution for millions of women providing a compelling opportunity to add significant economic and social value.



**Sources:** NCBI, National Association for Incontinence and the Melior Insights Team



## MELIOR CAPITAL MANAGEMENT: PIONEERING LIFE SCIENCE INVESTMENT

- I. Investors and their advisers must be prepared that some investments could fail. Melior is only available through professional advisers for qualified investors who genuinely understand and accept risk. Investors should only invest money they do not need access to, and which they can afford to lose. No investment may be entered into, neither in part nor in whole, on the basis of this newsletter. This newsletter is not an offer nor an invitation to subscribe. Melior does not provide or imply investment advice.
- II. The views and opinions expressed within this document reflect those of our professional advisers, and are not necessarily those of Melior. Professional advisers should ensure that their clients seek independent and suitably qualified advice before entering into such investment.
- III. Members of the Melior Scientific Team have worked on and taken to market a large number of life science projects during their careers, which spans over the past forty years. Some projects added additional revenue streams to an existing big pharma patent portfolio, some were trade-sales and some were IPOs.

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