JANUARY 2025

EXECUTIVE SUMMARY

rethink medical

1. Company Description

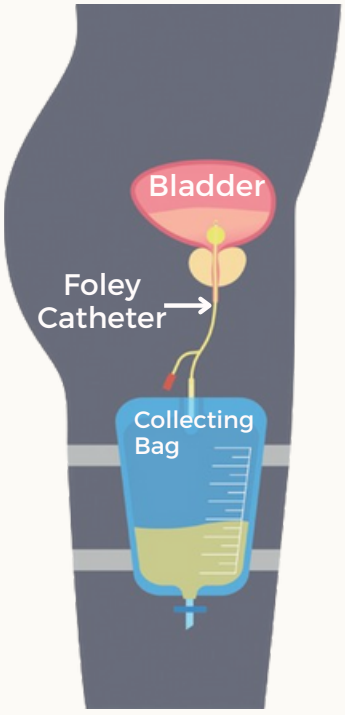
Rethink Medical was founded in 2014 at the Science and Technology Park of Las Palmas de Gran Canaria, Spain, with the purpose of addressing unmet needs in the healthcare sector by focusing on the development of **innovative medical devices**. Our flagship product is **T-Control®**, a **urinary catheter with an integrated fluid control valve** invented by Manuel Luque during his professional experience. **The product addresses the high risks and adverse effects associated with conventional catheters**, which have remained largely unchanged in design for nearly 100 years. Our approach is centered on creating an effective and accessible solution, without resorting to overly complex or costly technologies.

Quality of life

The startup combines the extensive **clinical expertise** of one of its co-founders, Manuel Luque, a nurse with over 16 years of experience, with the business vision of the other co-founder and CEO, Szilvia Endrényi, an economist and **marketing and business development expert** with a 15-year career in the pharmaceutical industry.

2. Market Problem

The use of conventional urinary catheters incurs a high health and economic burden on both patients and healthcare professionals/healthcare system. The main challenges include:



- **High Risk of Urinary Tract Infections (CAUTI):** Catheter-associated infections are among the most common and serious complications, increasing patient morbidity and mortality. They lead to prolonged hospital stays, extended use of antibiotics, and, in some cases, sepsis.
- **Reduced Quality of Life for Patients:** Traditional catheters require the use of collection bags, limiting patients' mobility and autonomy, and negatively impacting their psychological, social, and physical well-being.
- **Usage Challenges and Occupational Risks for Healthcare Professionals:** Handling catheters and their drainage systems is a complex procedure where losing aseptic conditions can have severe consequences linked to infections. Additionally, healthcare workers are exposed to biological fluids, increasing the risk of infections and contamination, as seen during outbreaks like Ebola and the COVID-19 pandemic.
- **High Healthcare and Social Costs:** Adverse effects associated with catheter use significantly raise costs, including hospitalizations, treatments, materials, follow-up visits, reduced quality of life, and caregiving expenses.

In addition to these issues, at a **public health** level, we face high antibiotic consumption, which contributes to the global rise in antibiotic resistance. From an **environmental** perspective, the daily use of collection bags results in a significant amount of plastic waste.

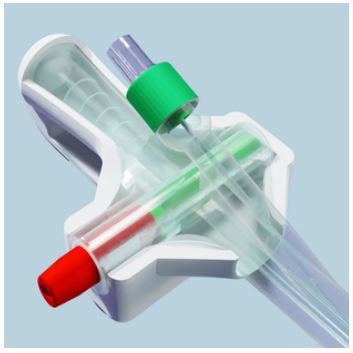
There is a clear **market need for innovative solutions** that not only improve clinical outcomes but are also **economically and environmentally sustainable**.

3. Solution

T-Control® solves the problems of conventional catheters by a smart design, consisting of a patented urinary catheter with a fully integrated fluid control valve that offers the following benefits:

- **Fluid Control:** The valve allows for intuitive and secure management of urine flow from insertion to removal.
- **Infection Prevention:** T-Control®'s design reduces biofilms, prevents cross-contamination, protects the bladder wall, and prevents accidental traction, all of which are potential causes of infection.
- **Ease of Use for Patients:** T-Control® has an intuitive and safe design, making it easy to handle for elderly patients or those with reduced manual dexterity, even with vision problems. Its design was created with feedback from real patients. The device can also be used with collection bags if needed, in a fully customizable way.
- **Ease of Use for Healthcare Professionals:** The catheter prevents accidental urine leakage and minimizes the physical and mental workload associated with insertion and handling, improving the overall efficiency of healthcare providers.
- **Holder Accessory:** The product includes an accessory that ensures easy and secure attachment to the patient's leg or underwear, increasing safety and allowing for more intense physical activities, including use in aquatic environments.

Integrated valve



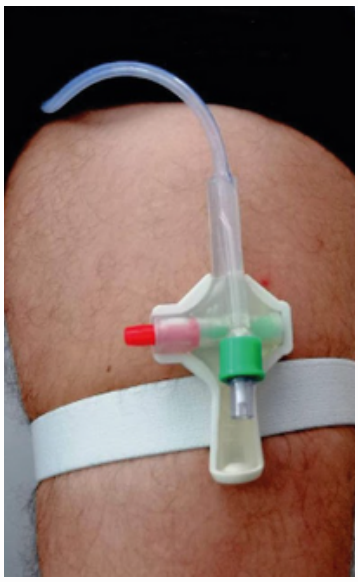
Patented

First Patent Family
Granted: Europe (EP2872194B1)
USA (US 9861780B2)

Second Patent Family
Pending: Europe, Japan and USA

Third Patent Family
Granted: Spain (ES2946438A1)
Pending: Australia, China, Canada, USA, Europe, Japan, South Korea

Holder



How to use T-Control®

Patient interview

4. Competitive Advantages

T-Control® is the first and only catheter with a fully integrated fluid control system. Its main competitive advantages include:

- **Closed System:** The valve enables intuitive and secure management of urine flow, providing a sealed system that ensures fluid output is controlled at all times.
- **Multifactorial Infection Prevention:** T-Control®'s design prevents infections through a unique, multifactorial approach without the use of new materials. It addresses both issues arising from the catheter design itself and those related to human errors.
- **Improved Patient Quality of Life:** By eliminating the need for external collection bags and offering an intuitive, easy-to-use design, patients gain autonomy and mobility, leading to closer to normal life with reduced negative impact from a psychological, physical, and social standpoint.
- **Healthcare Professional Efficiency and Protection:** The device reduces the risk of exposure to contagious diseases and facilitates the insertion process, allowing the procedure to be performed efficiently and safely, even with just one healthcare professional available.
- **Economic Savings:** The device reduces costs related to materials and adverse effects from conventional catheters.
- **Environmental Protection:** The device reduces plastic waste by eliminating the need for collection bags.

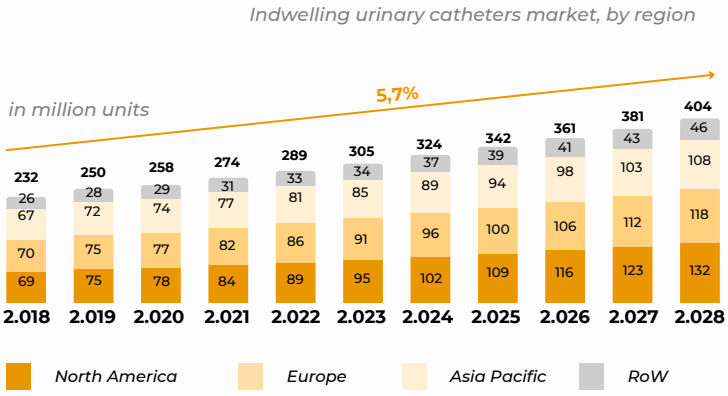
5. Target Market

The global market for urinary catheters is **continuously growing** due to factors such as the aging population and the increasing prevalence of urological disorders, including urinary incontinence and retention. It is estimated that this market will reach a value of approximately 4.1 billion dollars by 2028 with a 5.5% annual growth rate. **(Source:** MarketsandMarkets – Urinary Catheter Market Report)

Within this market, **T-Control®** positions itself as a **value-added solution** that not only improves quality of life and safety but also reduces the costs associated with complications from traditional catheters.

Our **target customers** are primarily:

- Hospitals and healthcare centers that acquire catheters through centralized purchasing processes or individual negotiations.
- Insurers and public administrations seeking to reduce costs associated with infections and prolonged hospitalizations.
- Patients, who increasingly have a greater influence on the selection of medical products, especially those that improve their quality of life.



Source: MarketsandMarkets – Urinary Catheter Market Report
Atrineo Technology Minds Market - Market Research

6. Traction and Achieved Milestones

Rethink Medical has achieved significant milestones, both in the validation of **T-Control®** and in attracting strategic partners and funding:

PATENTS	The product is protected by strong intellectual property, with 3 patent families.
ISO 13485 CERTIFICATION	Quality management system approved for the development, manufacturing, and marketing of medical devices.
MANUFACTURING	The product design has been optimized, and it is now being manufactured under real-world conditions in a system prepared for large-scale production.
PRE-CLINICAL STUDIES ON SUPERIORITY AND SAFETY	Several studies have confirmed the added value of the product and its safety. These studies have been published in scientific journals (8 articles published) and presented at international conferences (EAU/N, ICS Congress), garnering the attention of our future customers.
IN VIVO PILOT CLINICAL TRIALS	Conducted at leading hospitals such as the 12 de Octubre University Hospital and the University Hospital of Canarias, where the first versions of T-Control® were evaluated in over 20 patients.
COST/EFFECTIVENESS MODEL	An interactive Markov model was developed to calculate and justify the premium price of the product. The aim of the model is to demonstrate that, although the unit cost is higher than the cost of the currently used product, it results in savings in terms of "total patient cost per month" due to its added value.
EUROPEAN FUNDING RECEIVED	A €1.5M grant linked to EIC Accelerator was approved in 2023 for conducting an international multicenter study across 6 hospitals, clinically validating T-Control® and at the same time certifying it in the EU and the US. Previously, the company received support from SME Instrument Phase and EIT Health initiatives (Headstart, Innostar Awards, Living Lab/Testbed programs).
INVOLVEMENT OF KOLS	Support from Key Opinion Leaders at an international level
ONGOING NEGOTIATIONS	We have attracted the interest of multinational companies to license our product.
AWARDS AND RECOGNITIONS	Winners of the EIT Health Headstart program in 2017, finalists of the Innostar Awards in 2022, SME Instrument Phase I in 2018, selected among the 100 best startups by APTE in 2023, and recognized as 24 Changemakers by Forbes in 2024, among others.
FUNDING	€3.9 million raised to date.

7. Commercial Strategy

The commercial strategy consists of two phases:

1) Pilot launch:

Since clinical results will not yet be analyzed and published at the time of European regulatory approval, a small-scale launch is planned in the hospitals most interested in the project.

	2024	2025	2026	2027	2028
EUROPE					
Pilot launch					
Sales in 000 units		0.240	3.840	0	0
Price		15	15/25		
Sales (000 EUR)		**4**	**95**		

During this period, **special promotional prices** are planned in order to lower the barriers of entry from economic point of view. These prices reflect the "residual risk" assumed by the hospitals and are determined by the current cost of materials (catheter + bags) needed by a patient for a monthly period (these costs usually exceed 15 EUR).

Since manufacturing costs are also higher in this case, the objective of the pilot launch is not to achieve significant profit. **This phase is more qualitative, aiming to analyze experiences and trends, generate knowledge, and initiate traction for subsequent stages in different types of patients.**

EUROPE	2024	2025	2026	2027	2028
Scale up					
Total Foley catheter market 000 units *	96,000	100,000	106,000	112,000	118,000
Market share			0.30%	1.50%	3%
Sales in 000 units			**318**	**1,680**	**3,540**
Price			**25**	**25**	**25**
Sales (000 EUR)			**7,950**	**42,000**	**88,500**
Royalty (5% sales)		**0**	**398**	**2,100**	**4,425**

2) International scale-up:

Once the **clinical results** are published and the **first trends of real-world use** from the pilot phase are observed, the international **scale-up** will be prepared **with commercial partners.**

The forecast for this phase is based on the size of the Foley catheter market and its growth dynamics.

The goal is to position ourselves in the market where the added value is maximized and it is easier to apply the desired premium price, this time without discounts and based on our **updated cost-effectiveness model**.

The prices (minimum 25-30 EUR) reflect both the **added value** and the need to **generate savings in the total costs associated with a catheterized patient**, while also ensuring higher margins than those currently available for all stakeholders in the value chain.

	2024	2025	2026	2027	2028
UNITED STATES					
Total Foley catheter market 000 units *	102,000	109,000	116,000	123,000	132,000
Market share			0.30%	1.50%	3%
Sales in 000 units			**348**	**1,846**	**3,960**
Price			**30**	**30**	**30**
Sales (000 EUR)			**10,440**	**55,350**	**118,800**
Royalty (5% sales)		**0**	**522**	**2,768**	**5,940**

Revenue in this phase will consist of **royalties** based on sales achieved. By this stage, we will have a lower production cost, directly invoiced to our partners, to ensure more aggressive margins.

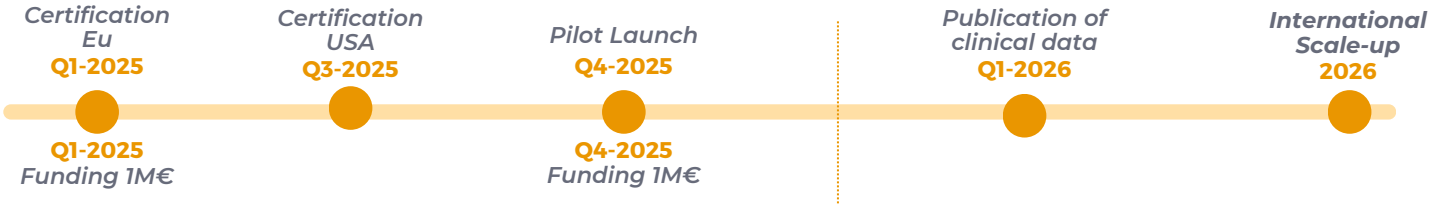
In contrast, significant **upfront payments for exclusivity (milestone payments)** will be applied, calculated through a reverse business case from the partner's perspective, ensuring an adequate ROI both for them and for our investors who opt for an **EXIT** during this period.

8. Financing and Next Milestones

A **€2M fundraising** is planned for **2025** to achieve our **two main milestones:**
1) **Pilot Launch**, 2) **International Scale-up.**

Use of funds

- Expenses related to an approved European grant for the 2023-2025 period (Grant)
- Structural expenses (personnel, maintenance regulatory costs, patents, and basic services)
- Expenses related to commercial activities (promotion, manufacturing, legal obligations, etc.)
- New certifications based on CE/FDA markings (for some countries in Asia and Canada)
- Financial expenses related to loan repayment



INCOME	2024	2025	2026	2027	2028	2029
Pilot sales (EU)	0	4	95	0	0	0
Royalty (EU & US)	0	0	0	920	4,868	10,365
Exclusivity / Milestone payment (EU & US)	0	0	0	20,000	0	0
Final income	169	0	156	0	0	0
Grants	832	235	0	0	0	0
Cash inicial / bank finance	339	0	0	0	0	0
TOTAL (000 EUR)	**1,340**	**239**	**251**	**20,920**	**4,868**	**10,365**
COSTS						
Costs related to Grants	709	1,125	0	0	0	0
Structural costs	84	420	550	550	550	550
Sales related costs	0	160	430	380	380	380
New market registration (Asia, Australia, Canada)	0	0	200	0	0	0
Financial costs	162	405	165	160	165	165
TOTAL (000 EUR)	**955**	**2,109**	**1.345**	**1,090**	**1,095**	**1,095**
INVESTMENT	610	2,000				
CASH FLOW (000 EUR)	950	129	-1,094	19,829	3,773	9,270
Accumulated CASH FLOW (000 EUR)		1,125	31	19,860	23,633	32,903

INVESTMENT OPPORTUNITY

FUNDING TO BE RAISED: **2M€**

- Certification in the EU & the US, with pilot launch: 1M€
- International scale-up: 1M€

EXPECTED EXIT:

- **2028-2029**
- **ROI: x10**

9. Team

Rethink Medical has a multidisciplinary team of highly qualified professionals committed to the development of **T-Control®**.

SZILVIA ENDRÉNYI
CEO/ CFO & CO-FOUNDER

Economist and marketing expert with 15 years of experience in the pharmaceutical industry.

MANUEL LUQUE
CIO/CTO & CO-FOUNDER

Nurse with over 16 years of experience and a deep knowledge of medical device innovation.

MARTA SERRANO
SCIENTIFIC AND REGULATORY DIRECTOR

Biologist with extensive experience in quality and regulatory affairs.

JAIME RUIZ
MECANICAL ENGINEER

Responsible for the design and quality of the product.

CLARA ARMAS
BIOMEDICAL

Researcher at Rethink Medical SL, specializing in biomedical validation and supporting the development of innovative medical devices.

MAX MÒDOL
BIOCHEMICAL

Biochemist specializing in R&D, clinical validation, and market preparation at Rethink Medical SL.

BRENDA GONZÁLEZ
MARKETING & DESIGN

Responsible for the creation of training and promotional materials.

ADVISORS

CARLOS BEZOS, PhD
PATIENT EXPERIENCE
Founder of the Patient Experience Institute

ORIOL SOLÁ, PhD
COST-EFFECTIVENESS AND MARKET ACCESS
Doctor, Founder and President of the HITT Foundation.
Former Director of the Health Technology Assessment Agency in Catalonia (AQUAS).

JOSÉ EMILIO BATISTA, PhD
UROLOGY / VALIDATION
Urologist - Teknon Medical Center / Uroclínica
Director of the Continentia Association

JOSÉ MEDINA-POLO
UROLOGY / VALIDATION
Urologist - Hospital 12 de Octubre
European Association of Urology (EAU) - Member of the Urological Infections Guidelines Committee

PEDRO SERRANO, PhD
VALIDATION AND MARKET ACCESS
Doctor
Former Director of Evaluation and Planning at the Canarian Health Service

HEIKO VISARIUS, PhD
MARKETING/SALES
MedTech expert
Founder of Visartis Healthcare
Former Commercial Director at Medtronic

JAN UTAS
DEVELOPMENT AND MARKETING
Expert in Urology and development of urological catheters
Former R&D Director at Wellspect Medical

MERCE VIDAL
PATENTS
Intellectual Property Expert
Director at Ponti Partners

XAVIER CANALS
REGULATORY
Regulatory Expert
Director of Tecno-med Ingenieros

ZOLTÁN KALÓ
COST-EFFECTIVENESS MODEL
Director of Syreon Institute

ÓSCAR ALEGRE
EXPERT LAWYER
Technology Transfer and IP. Ranked best lawyer 2020 in Technology in Barcelona

JIM FENTRESS
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Regulatory and medtech expert at Gilero

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