



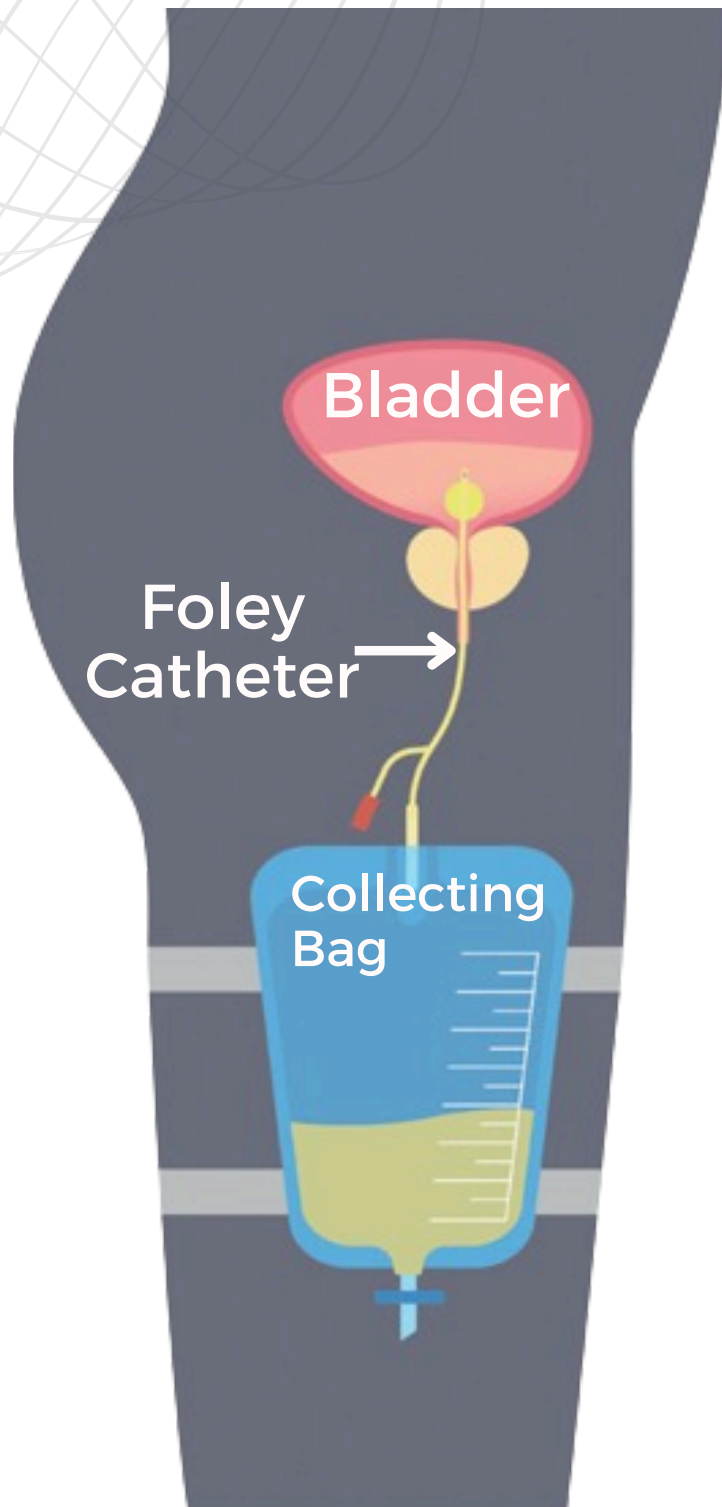
JANUARY 2025

THE NEW PARADIGM FOR URINARY CATHETERIZATION BASED ON NURSING EXPERIENCE

SMART DESIGN - HEALTHCARE REVOLUTION



WWW.RETHINKMEDICAL.ES



Quality of life



Emergency visits



Dependency



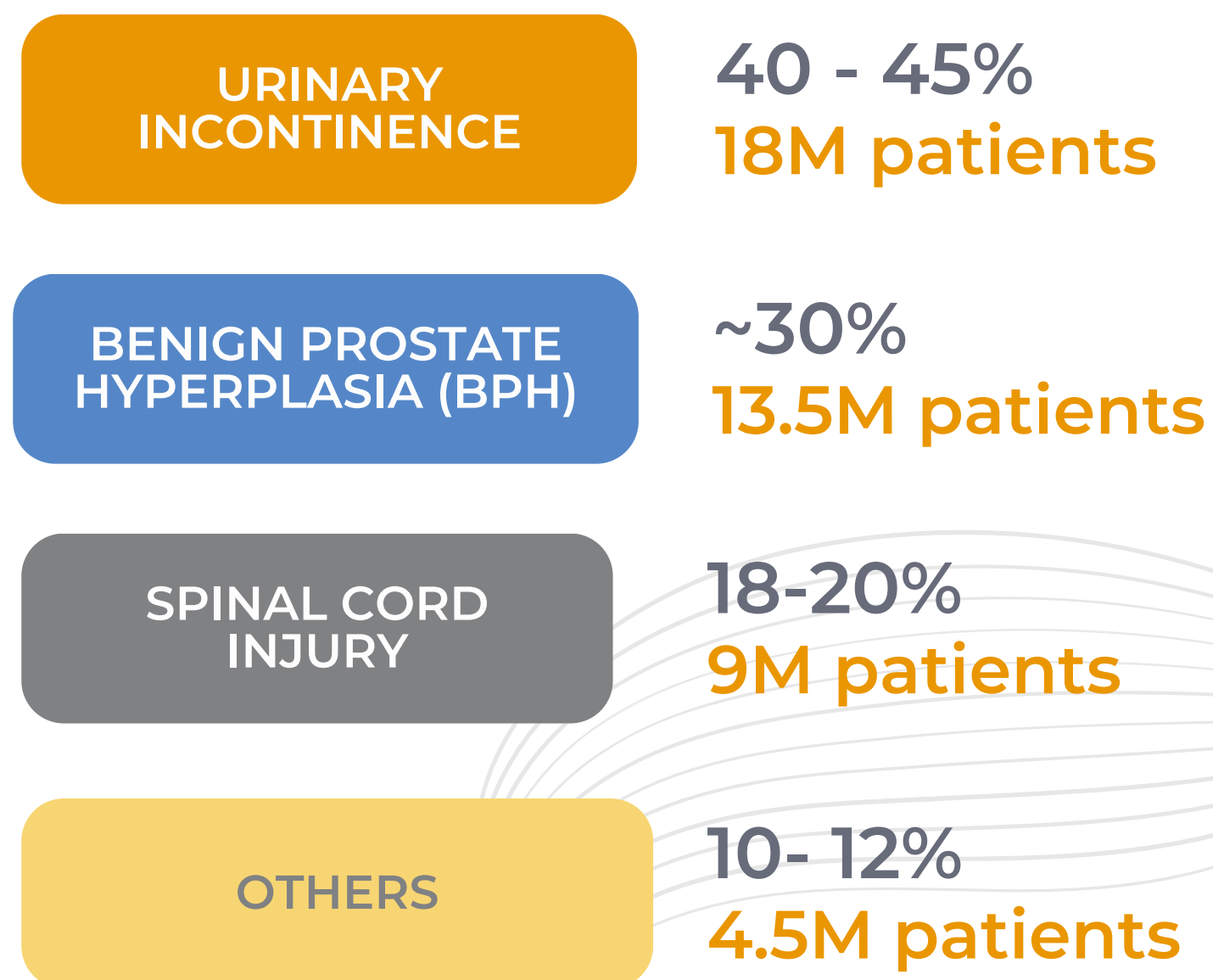
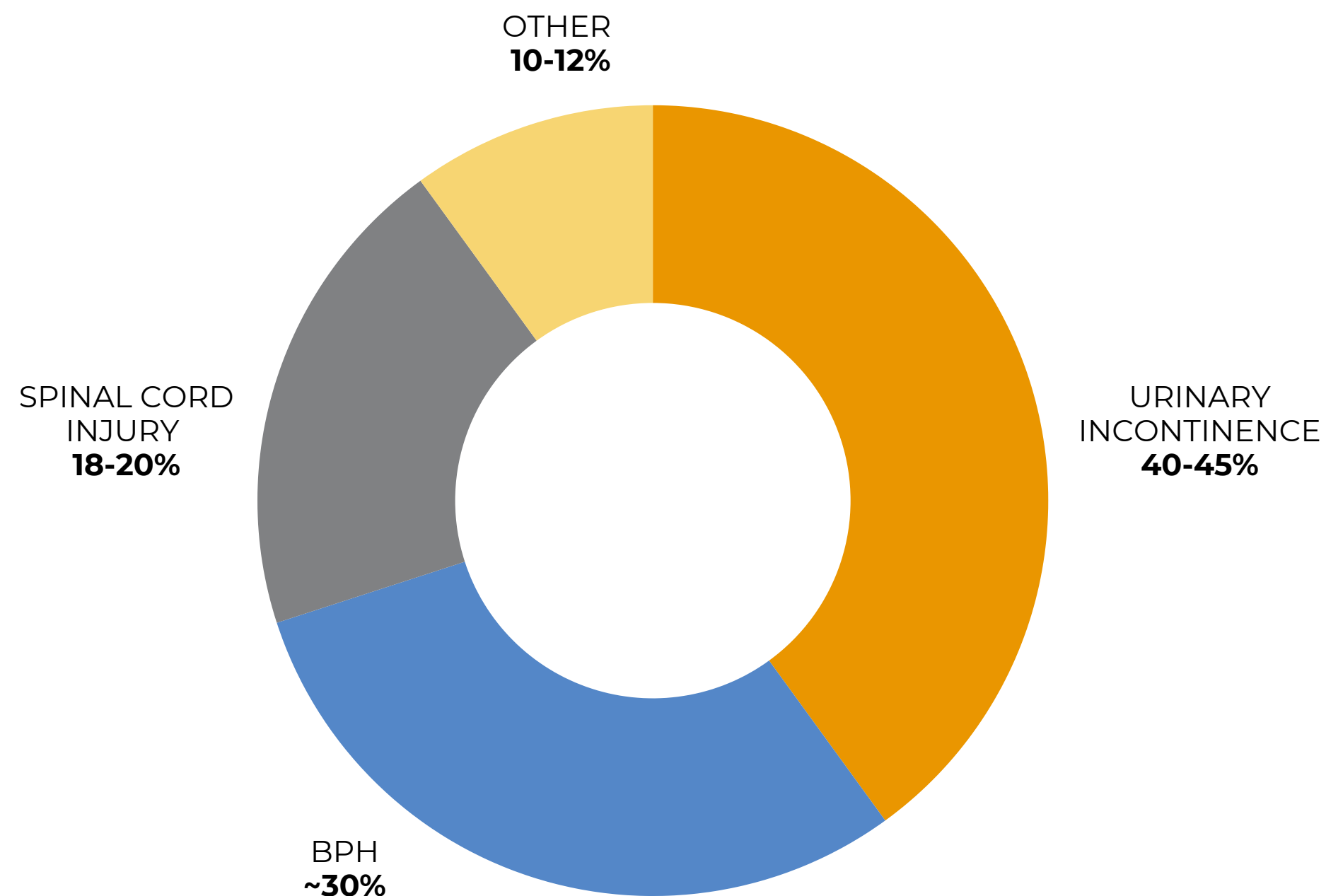
Infections of multifactorial origin

29.000 deaths/year
>900 M€ cost/year

Patient experience:



USER PROFILE (2030 - USA & EUROPE)



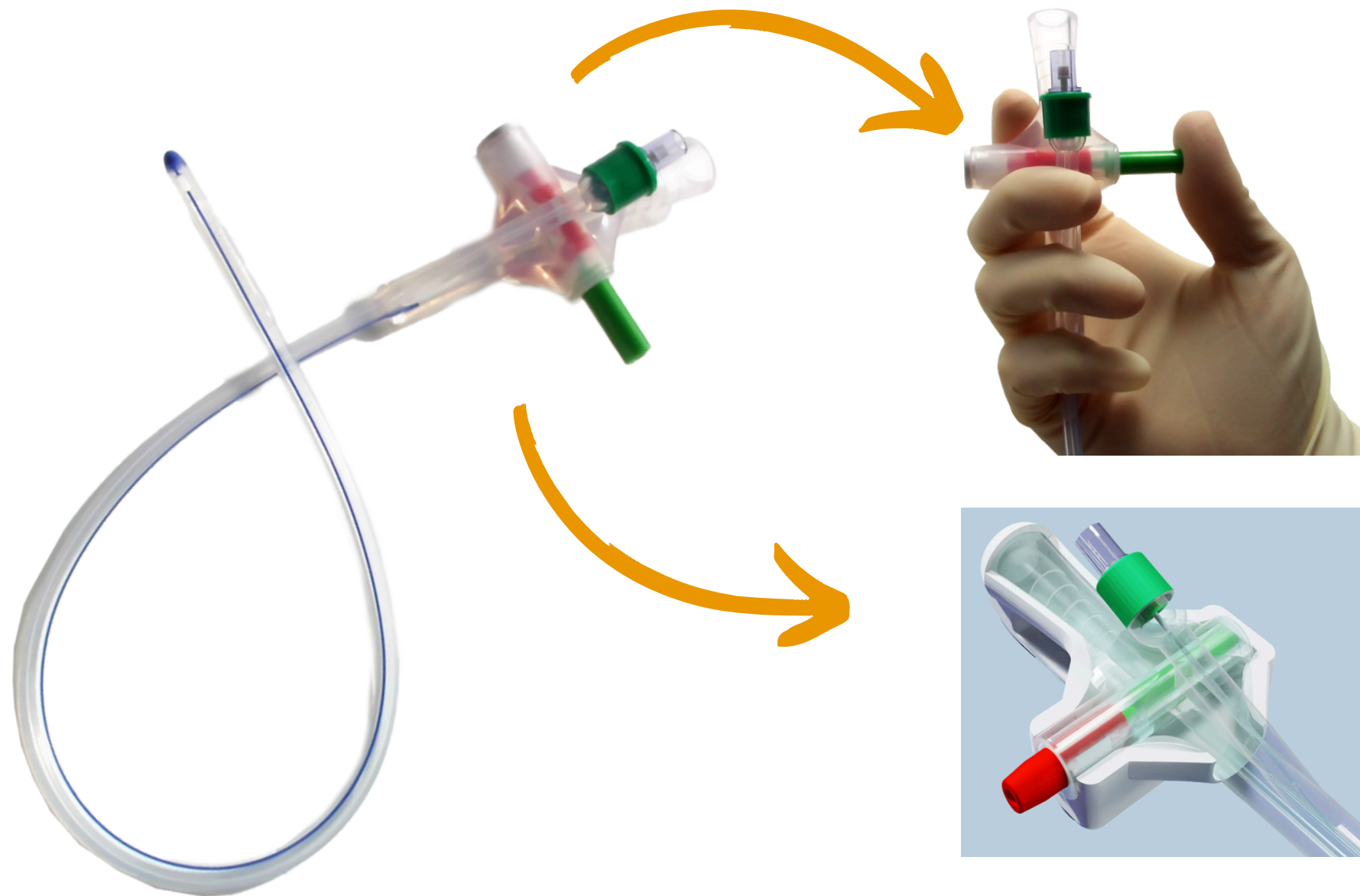
cca 45M PATIENTS

T-CONTROL®

*Fully integrated urine controlling system
No accessories needed for drainage*

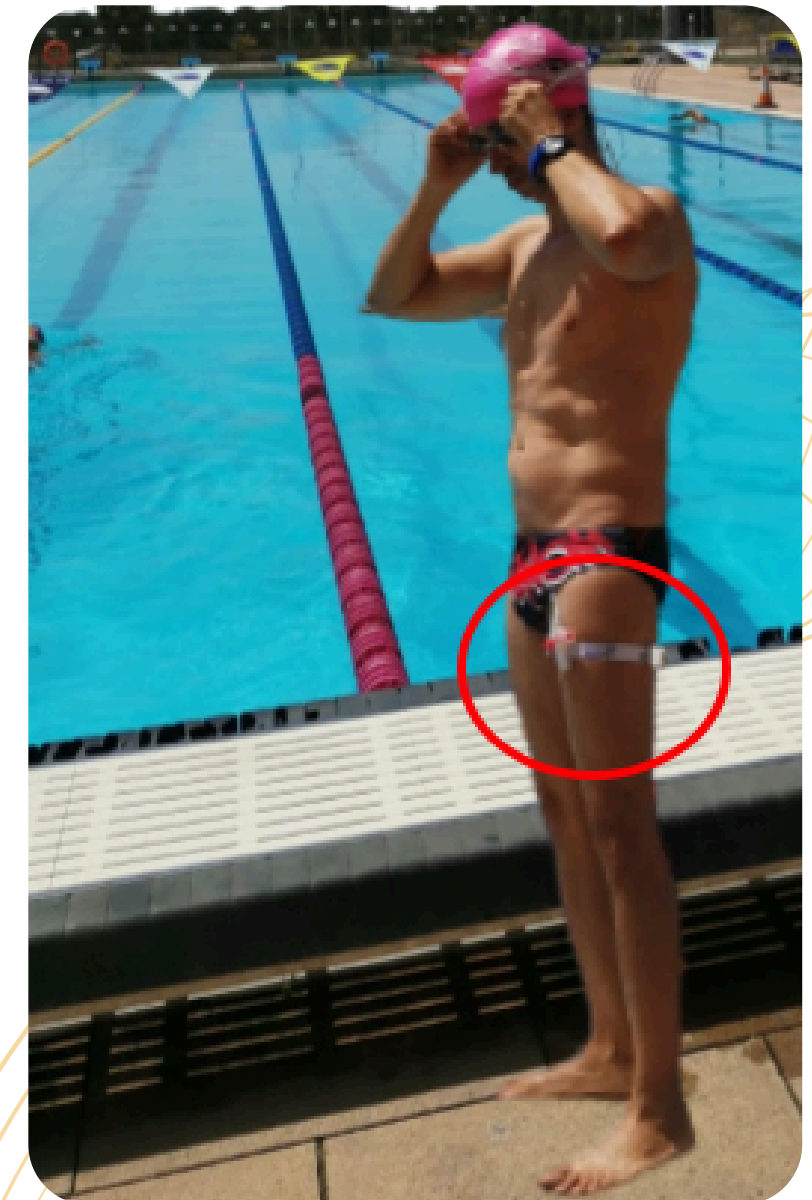
Multifactorial infection prevention and improved quality of life

How to use
T-Control®



**SLIDE VALVE FOR
OPENING AND CLOSING
THE URINE FLOW**

**HOLDER FOR
CATHETER FIXATION
AND SAFETY SEALING**



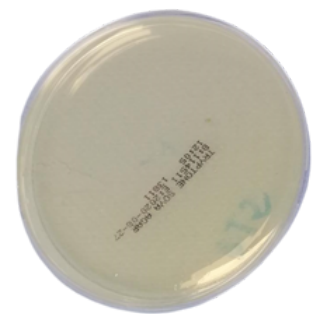
IN-VITRO VALIDATION

Significant differences confirmed regarding biofilm creation

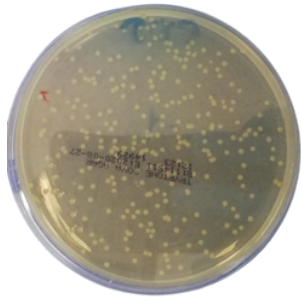
Article



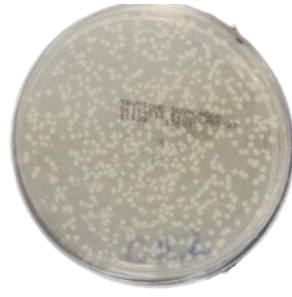
Common Foley +
bag



24h



48h



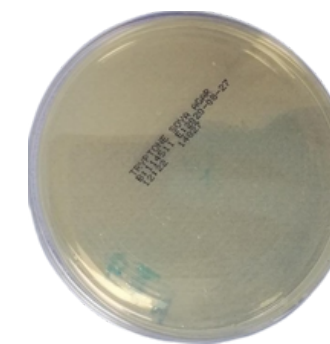
72h



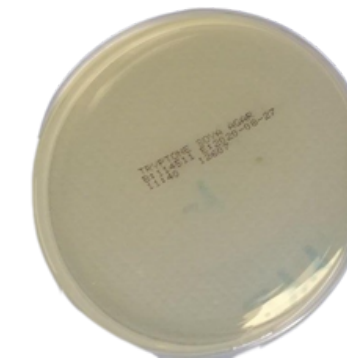
5 DAYS



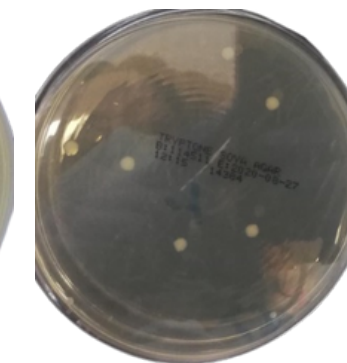
T-Control®



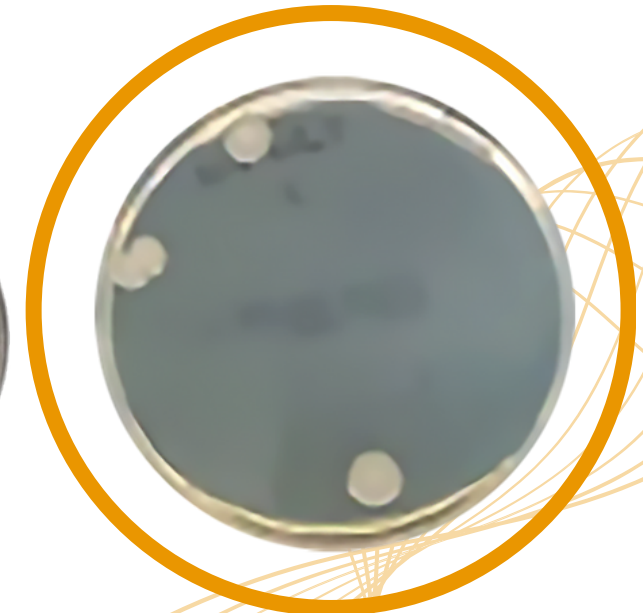
24h



48h



72h



5 DAYS

T-Control® expected to prevent 35-40% of today's infections.

USER TESTING RESULTS



HEALTHCARE PROFESSIONALS

41%

Less accidental spillages

23%

Decrease of cross-contamination

9%

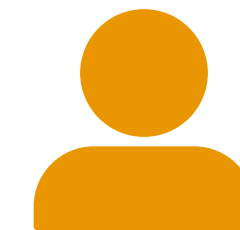
Lower mental effort ((NASA TLX)

12%

Lower Physical effort (NASA TLX)



Video
living-lab



PATIENTS

100%

Believe that it is easy and safe to use

100%

Agree that it provides added value



Article

CLINICAL VALIDATION

ONGOING STUDY

Comparative, Randomized, Prospective T-Control® vs Foley (Bag/Current practice): T-Control® vs Foley (bag). **n=** Total 70 (35. T-Control®/35. Foley Catheter) in 2 different sites.

Objectives: 1) Rate and magnitude of infections; 2) Quality of Life; 3) Usability and adverse effects; 4) Cost-impact.

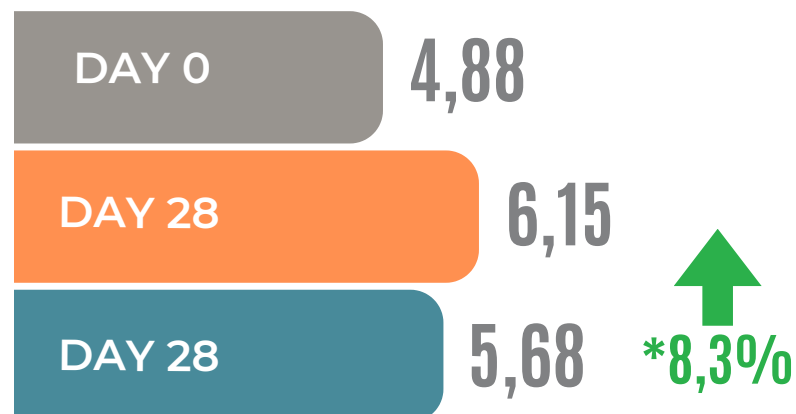
Patient profile: Ambulatory care - Chronic need of catheterization.

Poster

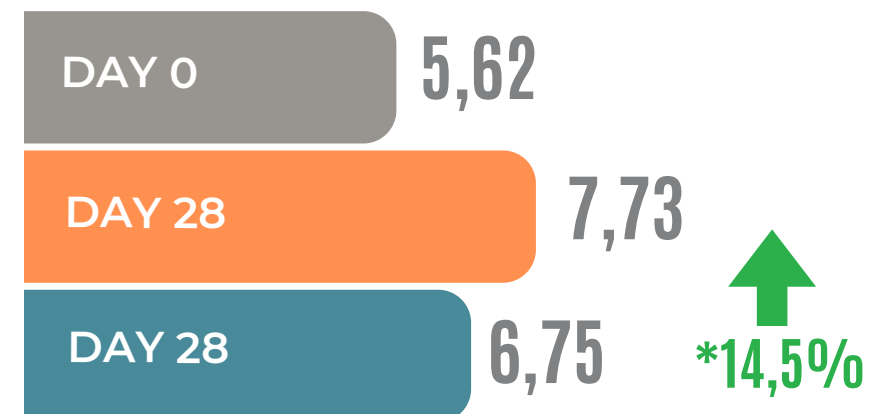


● Average of T-Control® & Foley groups ● T-Control® group ● Foley group

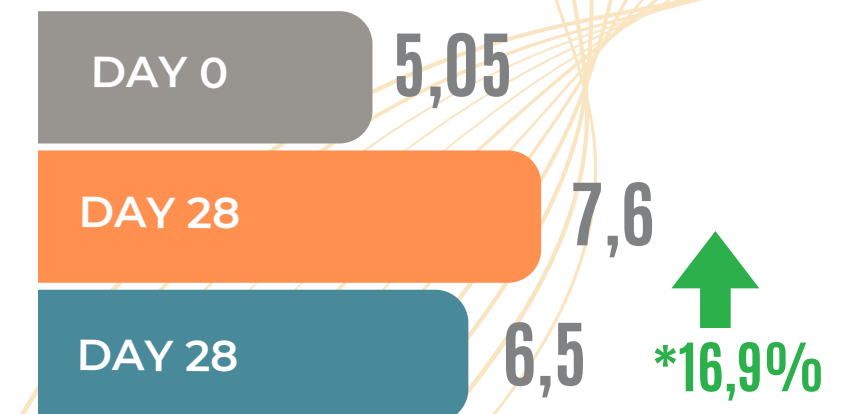
OVERALL QOL



POSITIVE IMPACT ON LIFESTYLE



SATISFACTION WITH THE CATHETER



Score from 1 to 10 (with 1 being the lowest and 10 being the highest)
Remarkably, no adverse effects have been reported

**Poster about preliminary results presented at ICS 2024 Congress*

CLINICAL VALIDATION

🕒 PLANNED FOR 2025

Comparative, Randomized, Prospective: T-Control® vs Foley (current practice)

Contries: Spain & Portugal

Recruitment initiation expected: Q1 2025

n Total 300 (150 T-Control®/150 Foley Catheter) at 6 different sites

Objectives: 1) Rate and magnitude of infections; 2) Quality of Life; 3) Usability and adverse effects; 4) Cost-impact.

Patient profile: Ambulatory care - Chronic need of catheterization.

IP & REGULATION

Strong Intellectual Property

1st patent:

Validated in 10 EU countries and the USA



2nd patent:

Filed in the EU, the US and Japan

3rd patent:

National phases: EU, USA & other countries.
Granted already in Spain

Trademark

Registered

Industrial design protection

Granted 2021

Simple Regulatory Approval



Regulation EU

2017/745 (MDR)
Ongoing
Expected approval: Q1 2025



Regulation USA

510(k) Pathway
Pre-sub meeting:
Q3 2023 & Q4 2024
Expected submission: Q2 2025



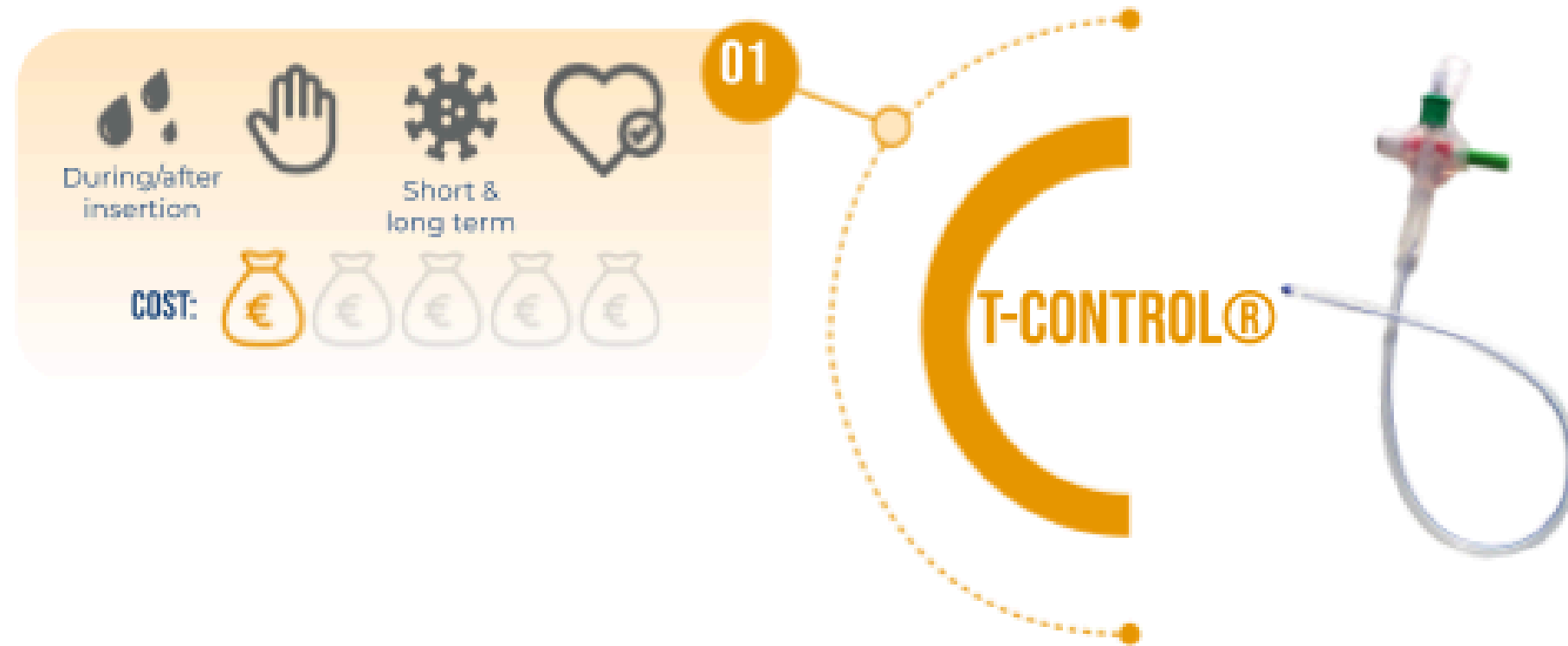
Quality system

ISO 13485

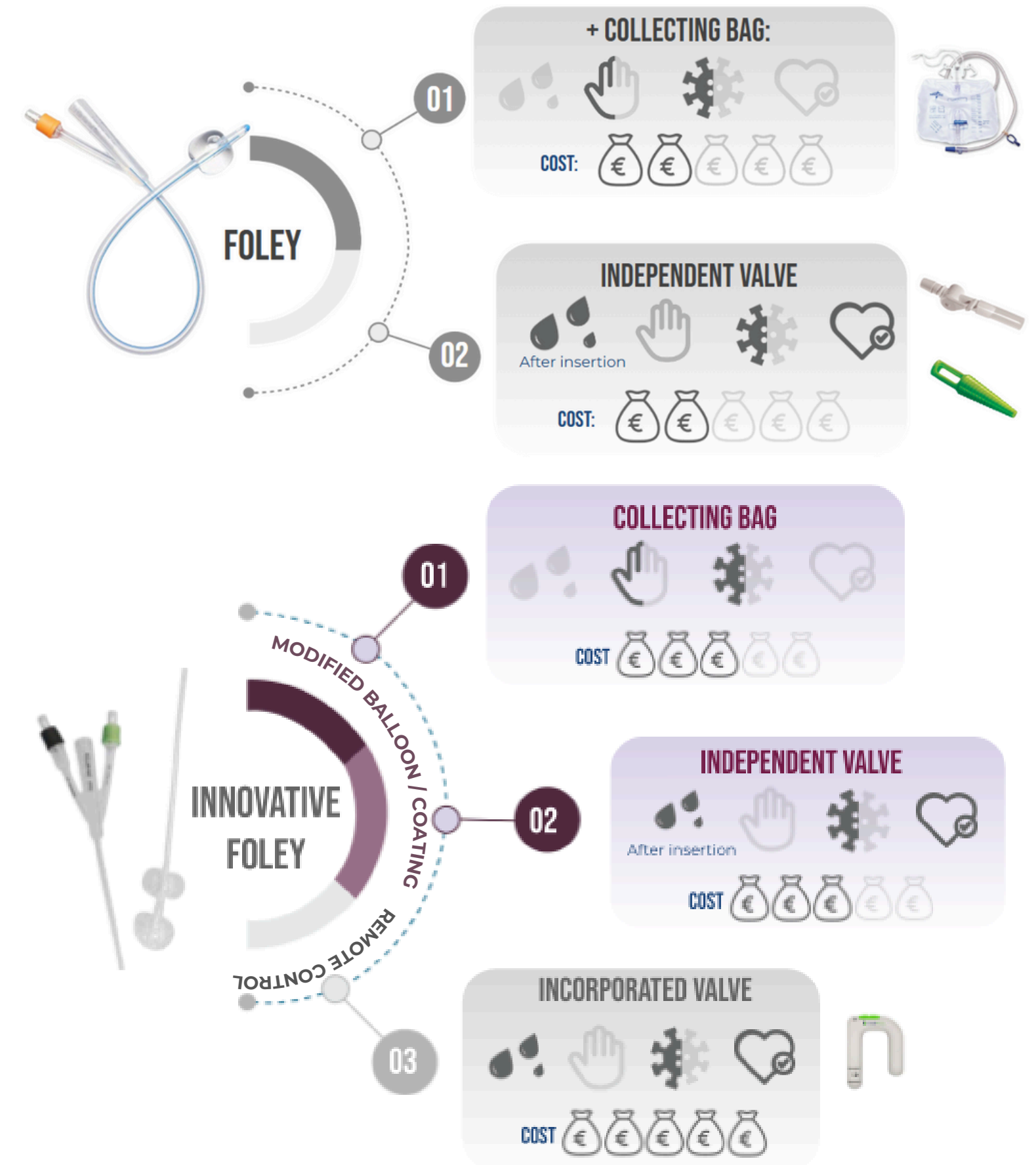
Approved January 2023



ADDED VALUE/COMPETITION



T-Control® – Designed for enhanced urine control, easier and safer insertion, lower risk of infection and Improved quality of life, with a favourable cost-effectiveness profile.



Health economic calculation

Markov economic model

Calculates the differential value of T-Control® vs. competitors, based on key drivers.

	Incremental cost	Incremental QALYs	
T-Control® vs Foley + Bag	23,212	1.84689	12,568
T-Control® vs Foley + Valves	16,411	0.92345	17,771

Costs taken into account:

- Unit cost of catheters, valves and bags
- Risk of infection & cost
- Quality of life & its value - QUALY of 20k EUR (valid in Spain)

Input data in our model (pessimistic version):

- 5-10% QoL improvement (preliminary clinical data)
- No improvement in infection prevention (still pending to be measured)
- 25 EUR unit price of T-Control®

Conclusion:

As ICER is lower than 20K EUR, **T-Control® is cost-effective against “Foley + bag” and “Foley + independent valves”** too.

T-Control® can be cost effective even at a higher price in case the results obtained in the clinical studies are better or in case other types of added value are taken into consideration during the price justification.

MAIN MILESTONES REACHED

- Clinical need demonstrated clearly
- Clinical approach validated with stakeholders
- Diverse, established and motivated team
- International recognition / funding
- IP / Brand assets
- ISO 13485 (BSI) / Risk management in place
- Approved clinical studies
- FDA Pre-sub meeting & US regulatory strategy 510(k)
- Close CE mark approval (TUV SUD)
- Cost effectiveness model (premium price justification)
- Clear commercial strategy
- Manufacturing / Sustainable pricing structure
- Scientific publications
- Existing KOL engagement
- Commercial partnering ongoing





DEVELOPMENT ROADMAP

- Completed
- Q4 2024
- Q1 2025
- Q2 2025
- Q3 2025
- Q4 2025
- Q1 2026
- Q2 2026
- Q3 2026
- Q4 2026
- Q1 2027
- Q2 2027
- Q3 2027
- Q4 2027

Pre-clinical validation

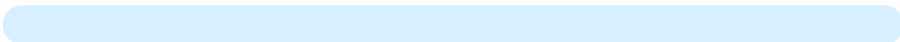


Quality system
ISO13485



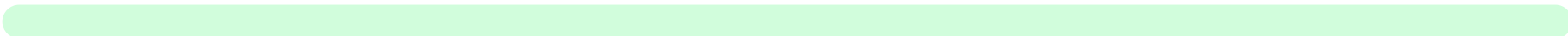
Certifications

- CE Mark + UKCA
- FDA
- Others



Clinical Validation

- Pilot study
- International study
- Others



Manufacturing

- Design
- Possible improvements/
industrial scale
- Line extension



Commercial Activities

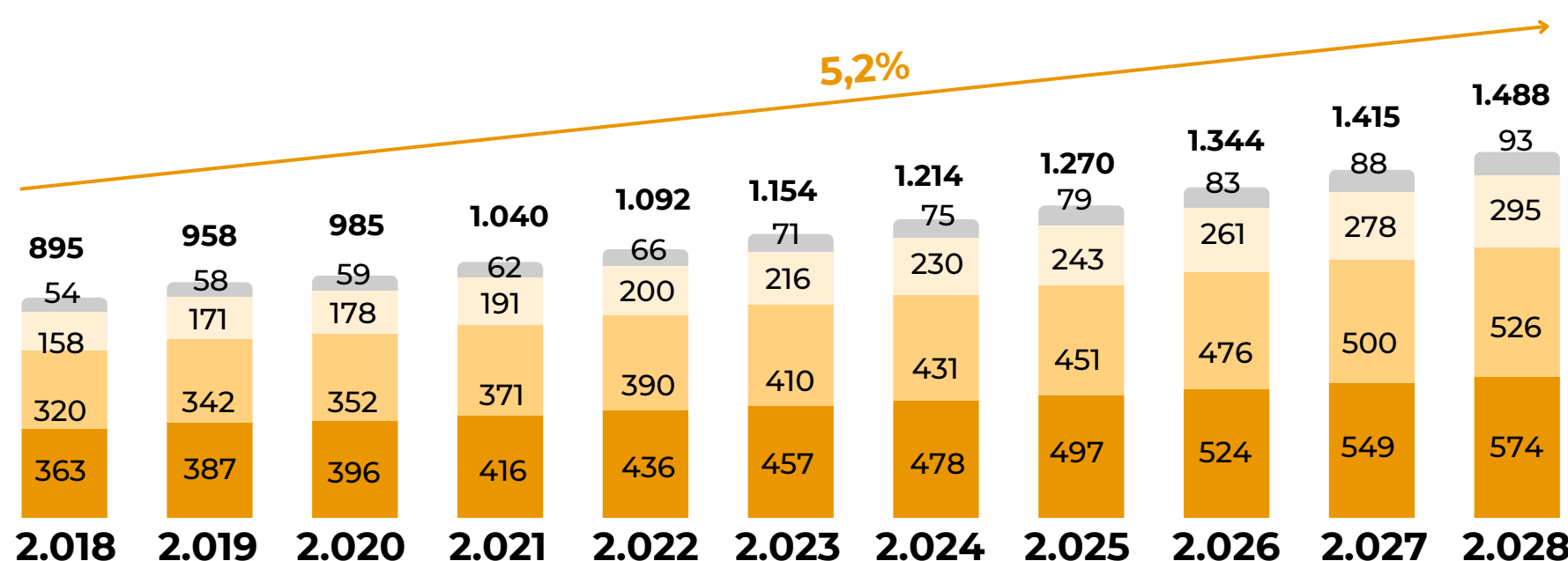
- Cost-effectiveness
model
- Pre-marketing
- Pilot distribution /
promotion
- Scale-Up international



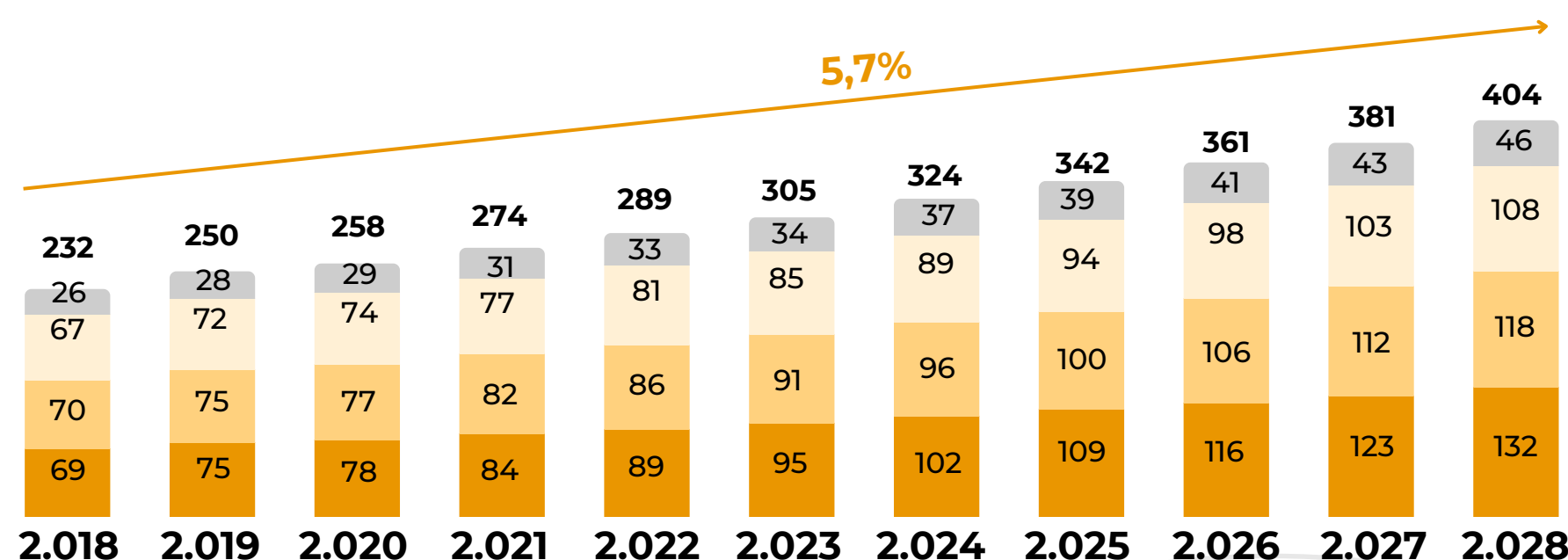
CURRENT SITUATION

Indwelling urinary catheters market, by region

In M€



In million units



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

Indwelling catheters (Foley), are expected to grow at a **CAGR of 5.7%**, reaching **404 million units by 2028**.

The majority of these units are distributed across **Europe** and **North America**, where advanced healthcare infrastructure supports their widespread use.

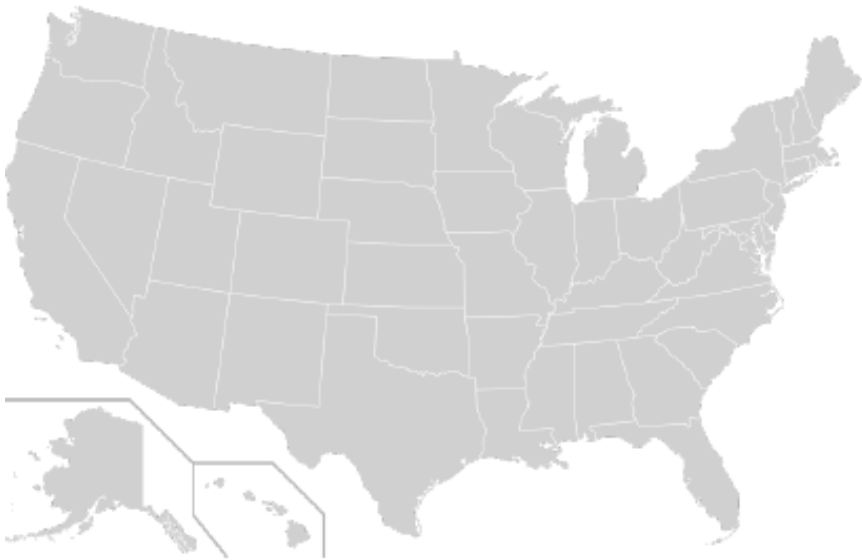
The **Asia Pacific** region is emerging as the fastest-growing market, driven by increasing healthcare access and the rising prevalence of conditions requiring catheterisation.



SALES EXPECTATIONS OF T-CONTROL®

	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		
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

	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



FINANCIAL PROJECTIONS - COMMERCIAL PARTNER

	2025	2026	2027	2028
EUROPE				
Sales (000 EUR)		7,950	42,000	88,500
Cost of goods (6 EUR)	0	1,908	10,080	21,240
Gross margin expected	0	6,042	31,920	67,260
Mkt and distribution costs (40%)	0	3,180	16,800	35,400
Royalty to be paid (5% sales)	0	398	2,100	4,425
Net margin	0	2,465	13,020	27,435

US				
Sales (000 EUR)		10,440	55,350	118,800
Cost of goods (7 EUR)	0	2,436	12,915	27,720
Gross margin expected	0	8,004	42,435	91,080
Mkt and distribution costs (40%)	0	4,176	22,140	47,520
Royalty to be paid (5% sales)	0	522	2,768	5,940
Net margin	0	3,306	17,528	37,620

TYPE OF COMPANY

Sector: Healthcare / Medical Devices

Experience: Established promotional, distributional and market access activity

Focus:

- Urology, GPs, Nursing Homes, Hospital
- Accelerate market entry and scale-up
- Expand international reach
- Reduce commercial risks and further funding needs

ADVANTAGES:

- Market presence without direct competitors
- Clear unmet needs to cover
- Large patient pool
- Premium price, without significant cost impact to clients
- Available publications for promotion
- Break-even in 2 years
- Significant ROI even mid-term

FINANCIAL PROJECTIONS - RETHINK MEDICAL

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						
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

**TOTAL FUNDING
RAISED: 3,9M€**

**NEW
INVESTMENT
OPPORTUNITY:**

AMOUNT*: 2M€

Milestones:

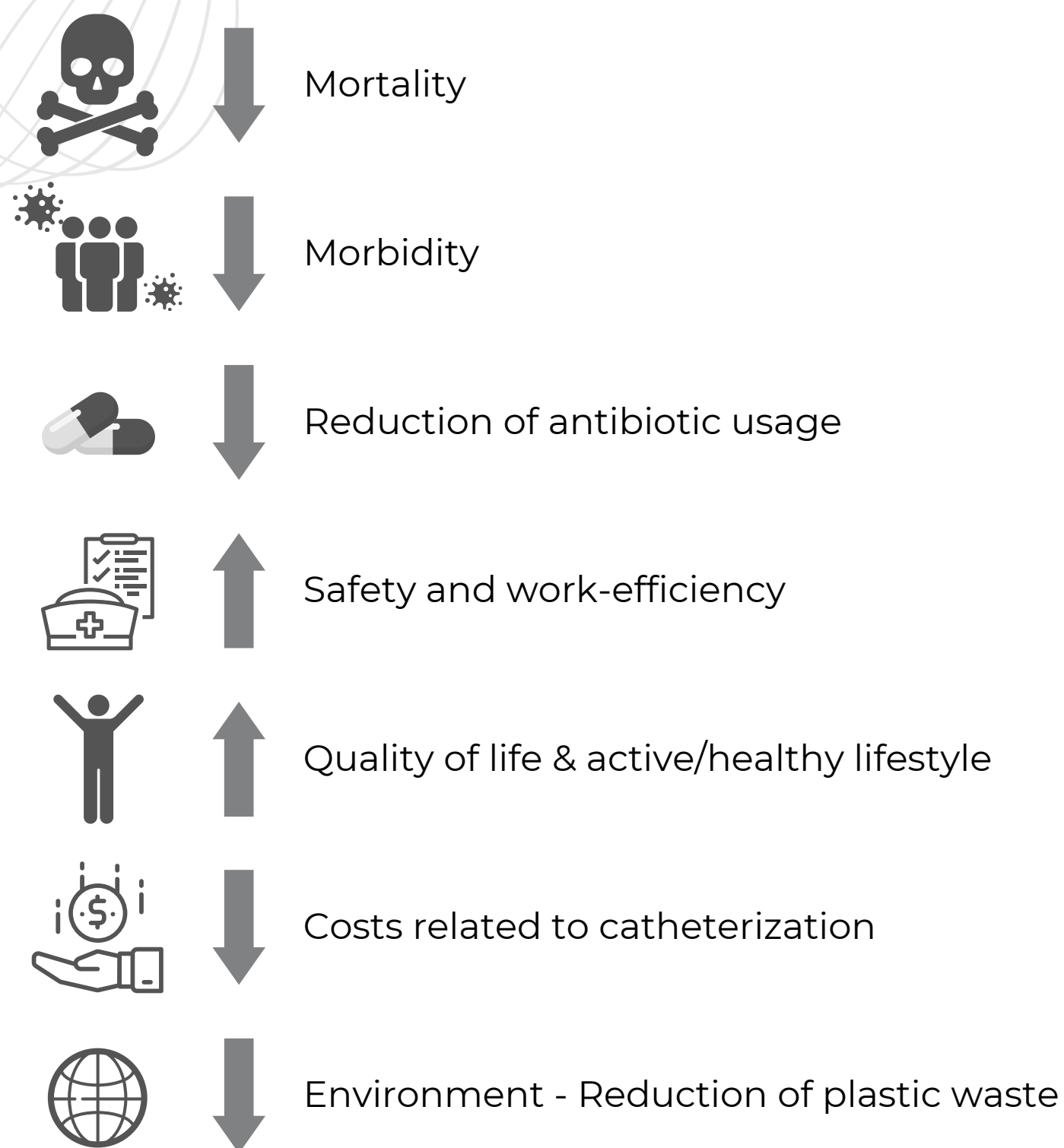
- Certification(EU & US) with pilot launch: 1M€
- International scale-up: 1M€

*Terms to be discussed

EXPECTED EXIT:

- 2028-2029
- ROI: x10

SOCIAL IMPACT OF THE INVESTMENT





THE PROBLEM

THE SOLUTION

MARKET

FINANCIALS

TEAM

THE TEAM



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.



MAX MÒDOL
PROJECT MANAGER

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



CLARA ARMAS
JUNIOR RESEARCHER

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



JAIME RUIZ
MECANICAL
ENGINEER

Responsible for the design and quality of the product.



BRENDA GONZÁLEZ
MARKETING & DESIGN

Responsible for the creation of training and promotional materials.

EXTERNAL TEAM



ROBERTO MORELL
INDUSTRIAL ENGINEER
Project management, public/private financing



ESTEBAN MESA
ECONOMIST
Financial management, business administration

ADVISORY BOARD



CARLOS BEZOS, PhD
PATIENT EXPERIENCE

Founder of the Patient
Experience Institute



ORIO SOLÀ, 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

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 IN TECHNOLOGY.

Technology Transfer and IP. Ranked best
lawyer 2020 in Technology in Barcelona



JIM FENTRESS
REGULATORY US/FDA

Regulatory and medtech expert
at Gilero

AWARDS

- 2016 Headstart (**Eit Health**)
- 2017 European Commission - **Sme Fase I**
- 2019 Best Entrepreneur - Canarian Island
- 2021 Innostars Awards (**Eit Health**)
- 2022 European Commission: **Seal of Excellence** EIC Accelerator
- 2023 Next Generation / EIC / CDTI (6th position in Spain)
- 2023 Best startup at Canarias Destino Startup
- 2024 Top 100 de startups in Spain (APTE)
- 2024 **Among the 24 Changemakers in 2024 (FORBES)**



COMPANY ACCELERATED BY:



EUROPEAN DISTINCTION:



LET YOUR MONEY MAKE A DIFFERENCE INVEST IN UROLOGY CARE



Szilvia Endrényi

CEO & Co-founder

szilvia@rethinkmedical.es

rethink
medical



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