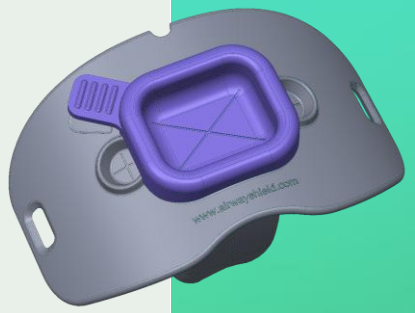
Airway Shield™

SAFER INTUBATION

for patients and clinicians



ENDOTRACHEAL INTUBATION

An Unresolved Medical Challenge

Endotracheal Intubation (ETI)

The 3rd Most Common Medical Procedure in Hospitals around the World
A High-Risk Life-Saving Procedure

45% of intubations in critically ill patients end up in **major complications** (hypoxemia, cardiovascular instability or cardiac arrest)

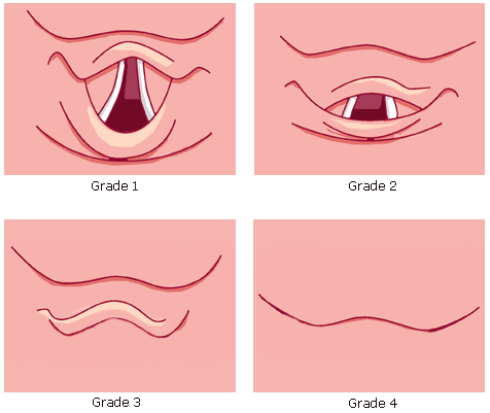
+100M intubations per year **worldwide** for all surgical and critically ill patients

$5.94B of **annual national cost** of peri-intubation morbidity and complications in the U.S.

Normal vs Difficult Airways (DA)

Difficult airway are the ones where those **complications are more probable to happen**. The manage of a **difficult airway** requires advanced planning and alternative tools and techniques, and presents increased risks of complications.

ANATOMICAL DA



Most cases of DA in
Anaesthesia

↓

± 5% of ETI are DA

PHYSIOLOGICAL DA

Most cases in
ICU

↓

± 90% of ETI are DA

SITUATIONAL DA

Most cases in
Emergency and Pre-Hospital

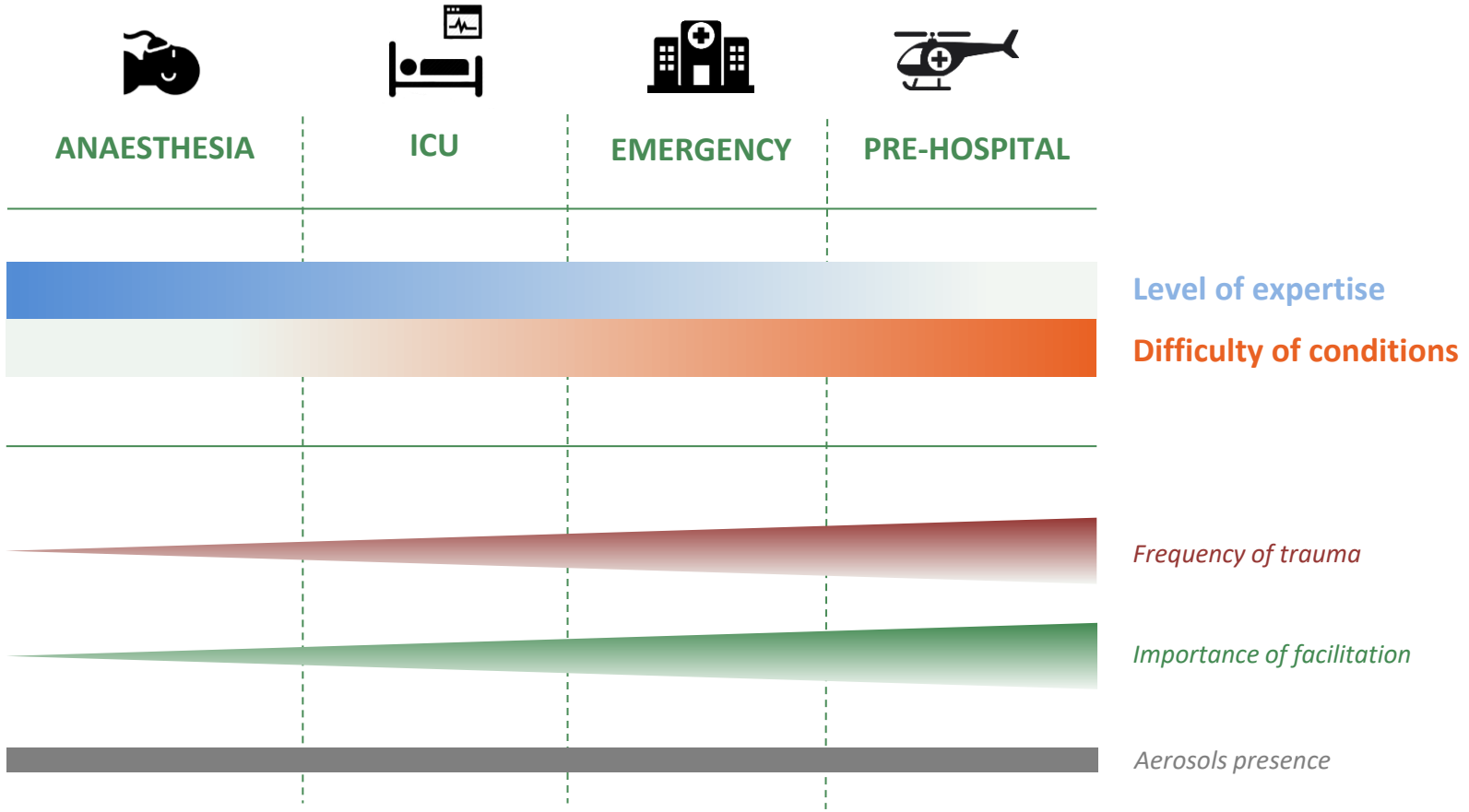
↓

± 100% of ETI are DA

ETI = Endotracheal intubation
ICU = Intensive Care Unit

ETI – Where is Performed?

Endotracheal Intubation (ETI) is performed during anaesthesia in Operating Rooms (ORs), in Intensive Care Units (ICUs), Emergency Rooms (ERs), and pre-hospital settings. Operators' level of expertise generally decreases outside the ORs, while the difficulty of conditions generally increases, particularly in pre-hospital settings.



SOLUTION

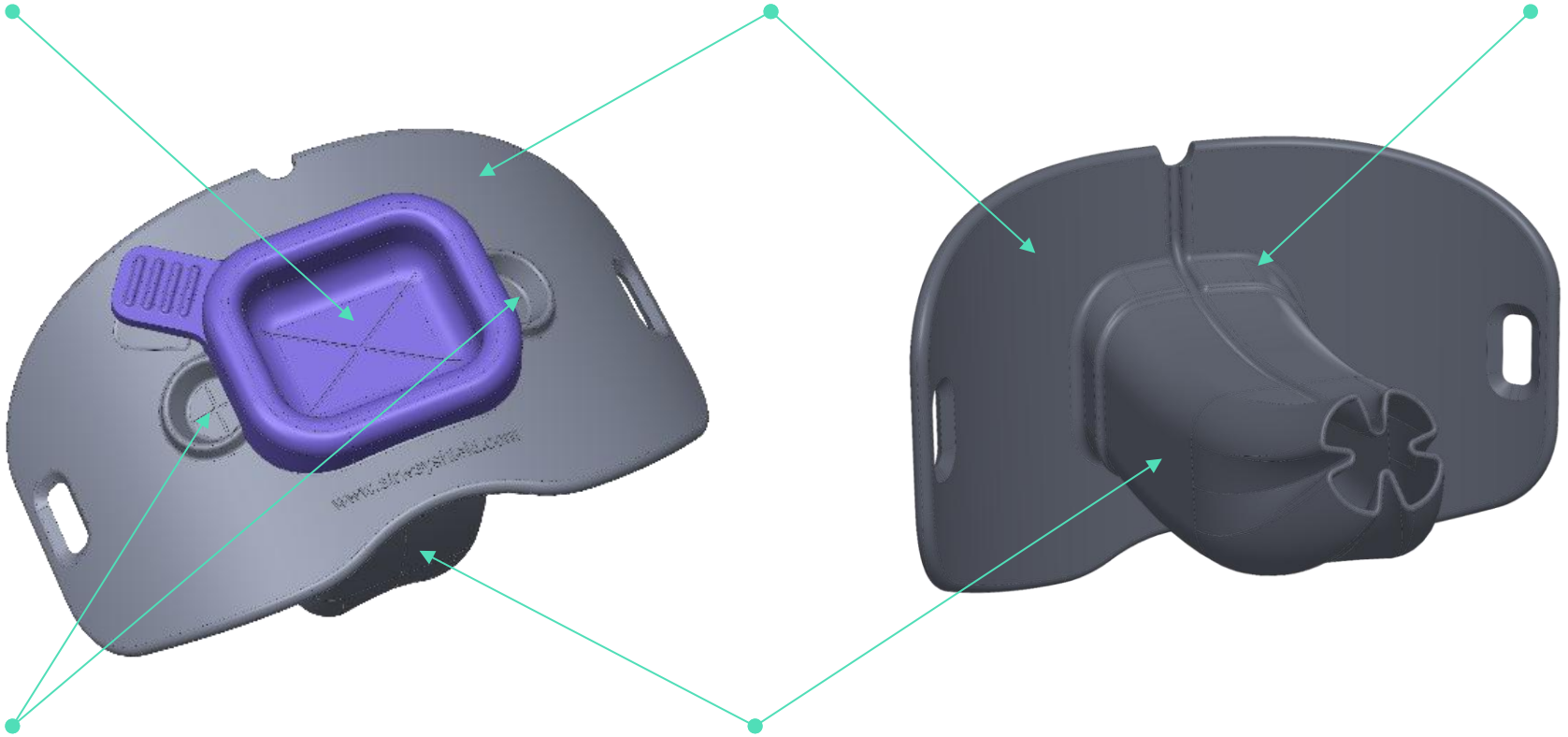
The SOLUTION for a Safer ETI: **Airway Shield™**

The world's first device **for endotracheal intubation that protects patients from dental and mucosa trauma**, **clinicians from aerosols**, and **guides the endotracheal tube** easily and simply into the trachea.

Sealed '**Central Opening**' to introduce the laryngoscope blade, followed by the ETT, to perform ETI

The '**Shield**' covers the patient's mouth and protects the operator from infection

A '**Reinforced Area**' also protects the teeth from damage during the ETI procedure

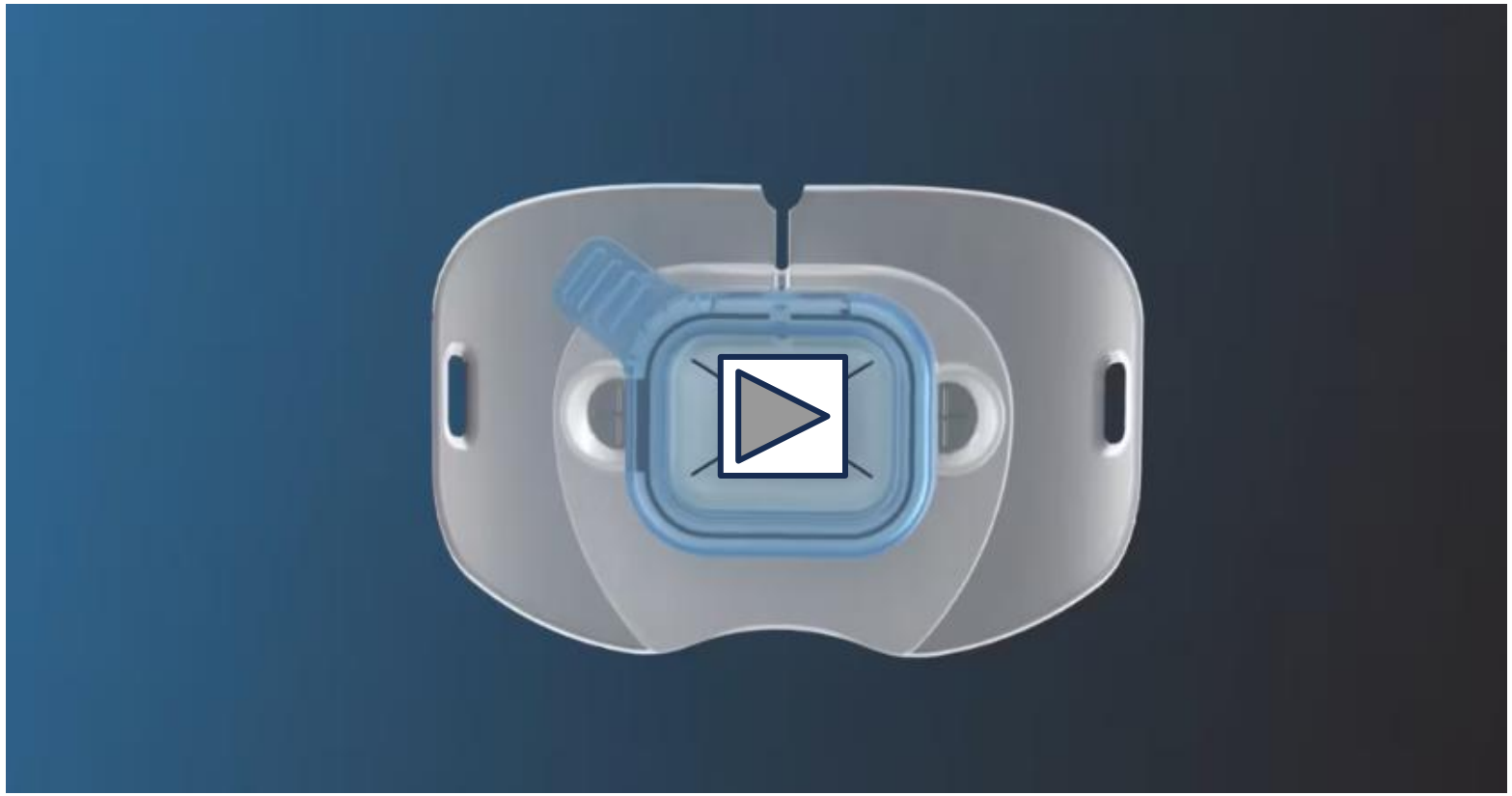


Sealed '**Lateral Openings**' to allow oxygenation and aspiration of secretions and/or aerosols

The '**Guiding-Channel**' facilitates intubation by guiding the endotracheal tube towards the larynx

Shield-Guided Technique™

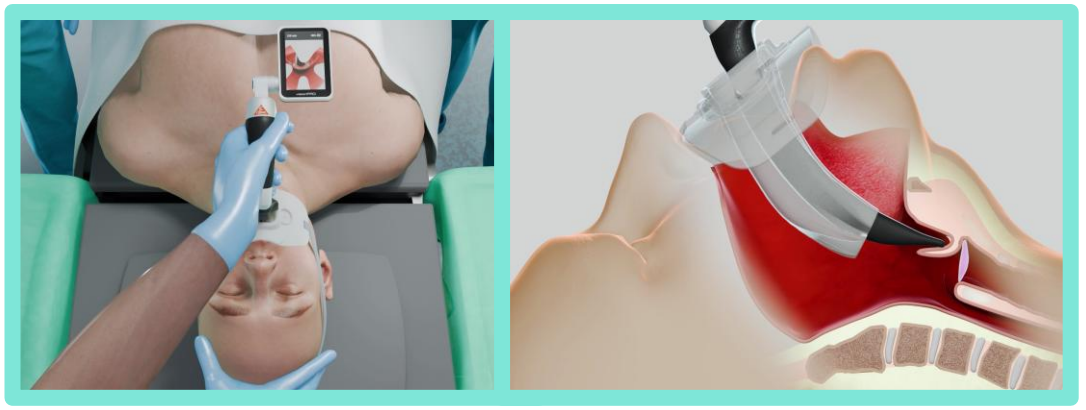
The Airway Shield™



The Airway Shield™

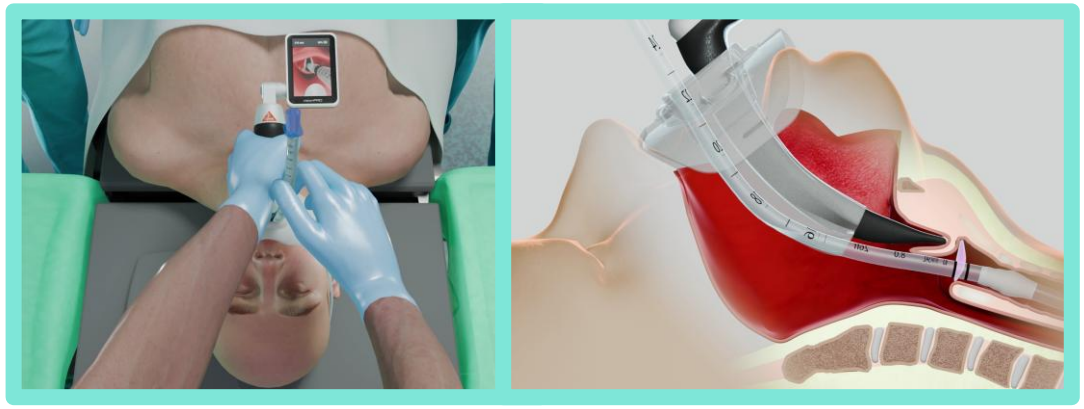
The simple yet innovative operating mechanism behind the **Airway Shield™** consists in supporting the tongue while creating a pathway for the endotracheal tube (ETT), so it can easily follow the direction set by the laryngoscope blade towards the larynx

1. Placement of the **Airway Shield™**



2. Introduction of the videolaryngoscope

3. [Ensure correct view of the glottis]



4. Introduction of the Endotracheal Tube

5.Removal of the videolaryngoscope

6. Removal of the **Airway Shield™**

The Airway Shield™

Endotracheal Intubation (ETI)

Airway Shield. What problem(s) we are solving?

1.

Complications: Adverse Events (AE)

45% (severe AE) in Emergency Intubations

- Death or disability
- Prolonged hospital stays
- Significant patient claims

2.

Complications: Airway Trauma

30% of total Anaesthetics Claims in US

- Patient pain and discomfort
- Frequent patient claims
- Extra costs for the hospital

3.

Health Systems: High Costs Access

Prehospital, Rural and Remote Areas

- Training costs
- Availability of Highly skilled Specialist
- System access

The Airway Shield™

Easier, Faster and Safer Intubation

PATIENT PROTECTION

Protects patient's teeth and mucosa

Dental injuries are frequent and much more likely in pacients with difficult airway[1]

Laryngeal injuries (19-27%), dysphonia (13-60%) and dysphagia (23-33%)[2].

1. *Tan, Y. et al., 2018*
2. *Kelly, E. et al., 2023*

GUIDED INTUBATION

Reducing intubation time by 50%[3]
Increases the first pass success

Increasing risk of **bradycardia and desaturation** as time increases[4]

3. *Alonso, Jm. et al., 2021*
4. *Nadler, I. et al., 2016*

CLINICIAN PROTECTION

Protects clinician from infection by decreasing 95% aerosols exposure[5]

5% hospitalized patients with COVID-19 were health care providers[6]

Up to **10%** of healthcare workers involved in COVID-19 ETI were infected[7]

5. *Alonso, JM. et al., 2022*
6. *Kambhampati, AK. et al., 2020*
7. *Weissman, DN. et al.,2020*

The Airway Shield™

Easier, Faster and Safer Intubation

PATIENT PROTECTION

GUIDED INTUBATION

CLINICIAN PROTECTION

Easy to use

For less experienced operators

Easy to learn

Minimal Training required

Low-cost

Simple solution to a complex problem.

Disruptive technology

Revolutionary and innovative desing

Patented

Design and method protected by an international patent.

Additional advantage of the Airway Shield™

Airway Shield™ reduces Dental Trauma during Endotracheal Intubation, the most common anaesthetic-related medical claim

Dental injuries are the most common anaesthetic-related event reported, accounting for up to 33% of the incidents[1,2]

86% of the injured teeth are the upper incisors, laryngoscopy being the major factor[3]

Dental injuries are much more likely in patients who are difficult to intubate (increasing chances from x3 to x20)[4]

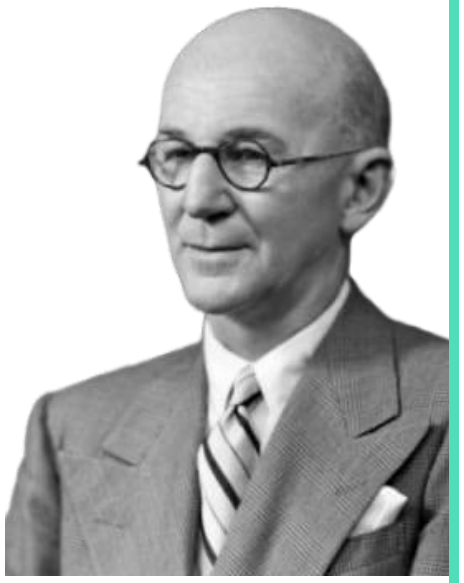
[1] Owen, H. & Waddell-Smith, I. (2000). Dental trauma associated with anaesthesia. Anaesthesia and intensive care, 28(2), 133–145. https://doi.org/10.1177/0310057X0002800202.
[2] Ranum, D. (2020). Anesthesiology Closed Claims Study. https://www.thedoctors.com/articles/anesthesiology-closed-claims-study.
[3] Ansari, S., Rajpurohit, V. & Deo, V. (2016). Dental Trauma due to Intubating during General Anaesthesia: Incidence, Risks Factors, and Prevention. Oral Health and Dental Management. 15(6). 377.
[4] Tan, Y., Loganathan, N., Thinn, K. K., Liu, E. H. C., & Loh, N. W. (2018). Dental injury in anaesthesia: a tertiary hospital's experience. BMC anesthesiology, 18(1), 108. https://doi.org/10.1186/s12871-018-0569-6

Changing the intubation paradigm

Airway Shield™ is a **disruptive technology**. Since the introduction of the laryngoscope in 1943 by Sir Robert Macintosh, there has been no change in the intubation paradigm.

Sir Robert Macintosh

1943 – Laryngoscope

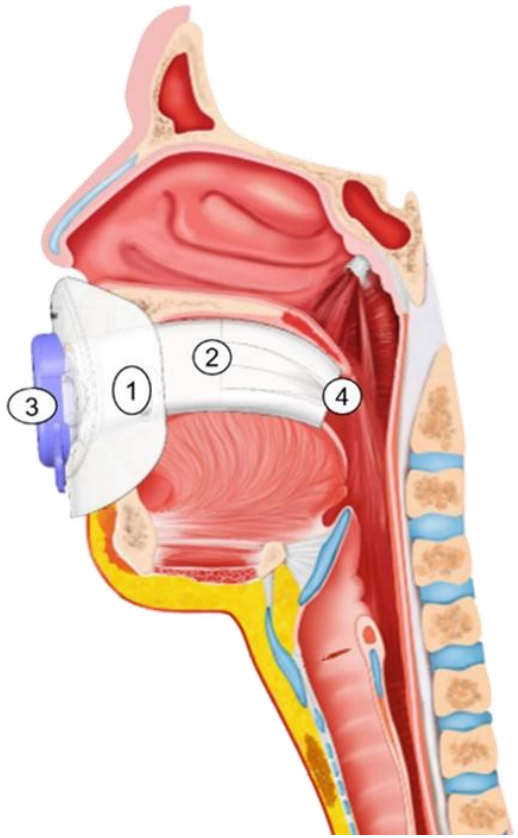


Macintosh laryngoscope

For the first time in history, a medical device, **Airway Shield™**, allows successful intubation with the patient's mouth covered.

The “Ideal” Guide for Intubation

Airway Shield™



According to Grape & Schoettker, 2017, the “ideal” device as an intubation aid should:

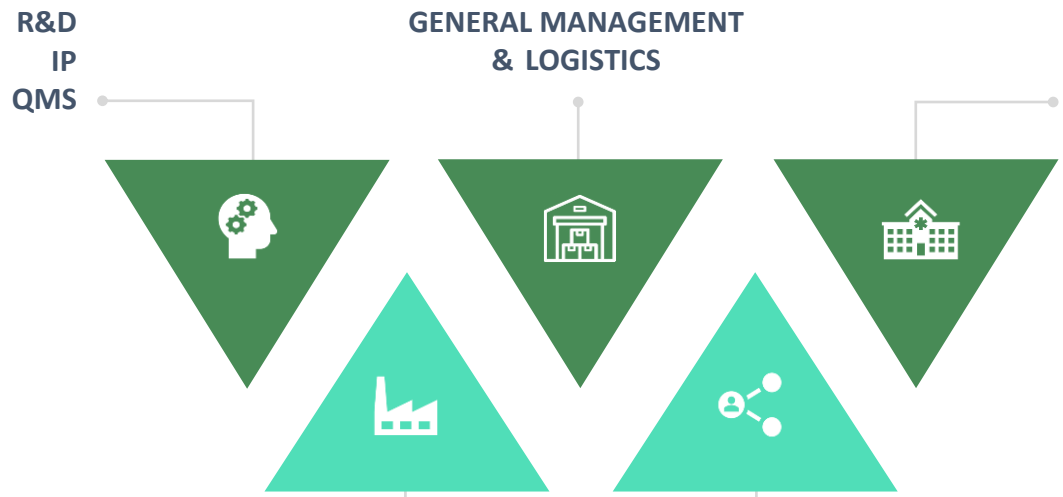
- Be inexpensive, readily available, single-use, easy to store and transport, and simple to handle.
- Be firm enough to maintain its shape after bending (memory effect), but soft enough not to cause airway trauma.
- Allow emergency oxygenation.
- Be compatible with videolaryngoscopy.

BUSINESS MODEL

Business Model

Airway Shield S.L. follows a B2B model. Our core business is IP management, R&D, Clinical Research and Marketing, and overall management and logistics, while manufacturing and distribution is externalized and tightly controlled by the company under an ISO13485 based QMS.

AIRWAY SHIELD CORE BUSINESS



PARTNERSHIPS

Business Model B2B

DISTRIBUTION AGREEMENTS

INTERNATIONAL TRADE

AWS TEAM

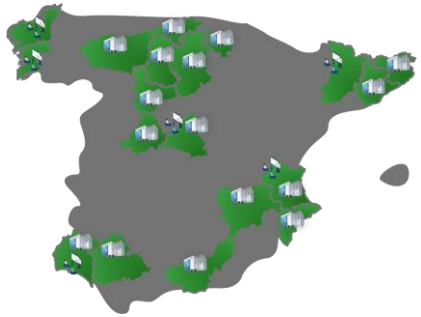
Train the distributor team

DISTRIBUTOR TEAM

Purchasing process
Marketing and Logistics

DIRECT SALES

NATIONAL TRADE



AWS TEAM

Sales Delegates

Train the Sales Delegates
Clinical sesions
Marketing and Logistics

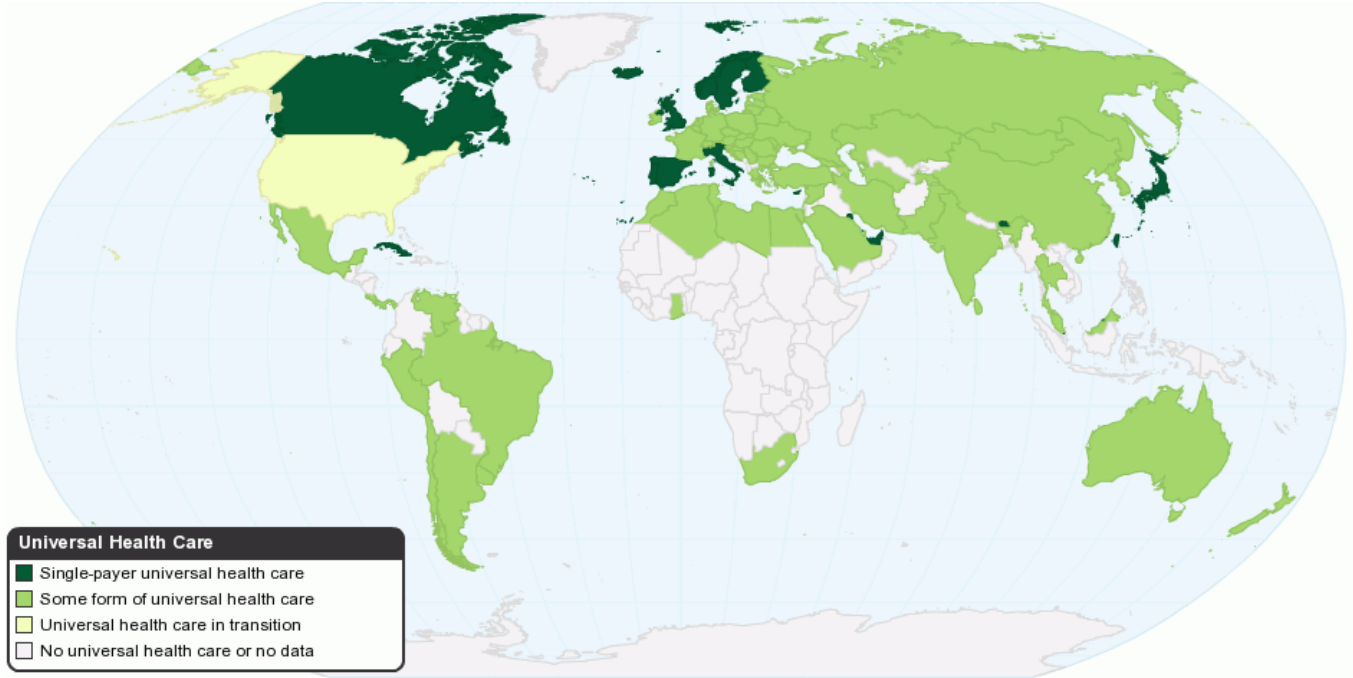
Purchasing process

Commercialization Strategy

- **Every healthcare system is different around the world.**
- **Our smart business model takes this into account.**
- **To this purpose:**

  We work with the best distributors in each country, who know and manage their health model.

  Airway Shield will recruit experts in international commercialization.



WHO 2008, The world health report 2008 : primary health care now more than ever, ISBN 978 92 4 156373 4, World Health Organization, Geneva 27, Switzerland.

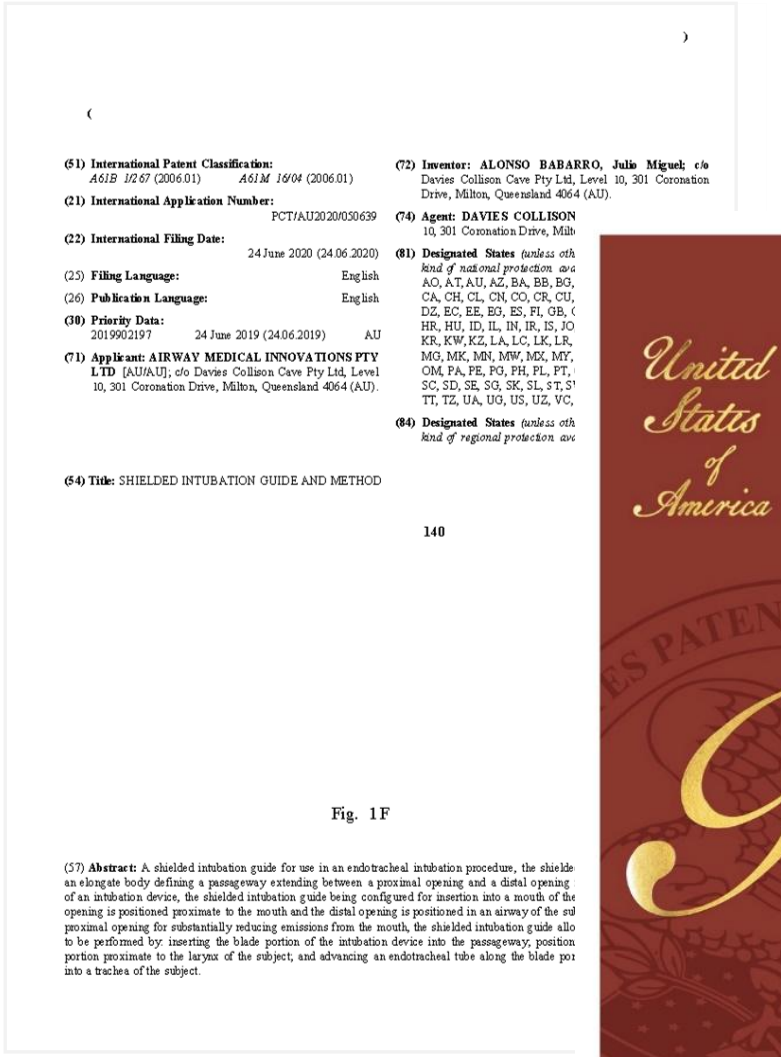
IP

Airway Shield™ is Patented Worldwide

- The international patent we hold is **strong** and **robust**.
- Patent protects not just the device but also The **unique intubation technique:**
  - Covering the mouth,
  - intubating through a channel,
  - with videolaryngoscope (this is the only viable method of intubation when the mouth is covered)
- The patent covers 90% of the **world market**.
- **National phases** advanced worldwide. **US** and **Japanese** Patents already **granted** in 2025**.** The remaining jurisdictions are expected to be completed by 2026.

PATENTED

International Publication Number: WO 2020/257851 A1
Jurisdiction: International (PCT)



(51) **International Patent Classification:**
A61B 1/267 (2006.01) *A61M 16/04* (2006.01)

(21) **International Application Number:**
PCT/AU2020/050639

(22) **International Filing Date:**
24 June 2020 (24.06.2020)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
2019902197 24 June 2019 (24.06.2019) AU

(71) **Applicant: AIRWAY MEDICAL INNOVATIONS PTY LTD** [AU/AU]; c/o Davies Collison Cave Pty Ltd, Level 10, 301 Coronation Drive, Milton, Queensland 4064 (AU).

(72) **Inventor: ALONSO BABARRO, Julio Miguel;** c/o Davies Collison Cave Pty Ltd, Level 10, 301 Coronation Drive, Milton, Queensland 4064 (AU).

(74) **Agent: DAVIES COLLISON** 10, 301 Coronation Drive, Milt

(81) **Designated States** *(unless oth kind of national protection ava* AO, AT, AU, AZ, BA, BB, BG, CA, CH, CL, CN, CO, CR, CU, DZ, EC, EE, EG, ES, FI, GB, HR, HU, ID, IL, IN, IR, IS, JO KR, KW, KZ, LA, LC, LK, LR, MG, MK, MN, MW, MX, MY, OM, PA, PE, PG, PH, PL, PT, SC, SD, SE, SG, SK, SL, ST, S TT, TZ, UA, UG, US, UZ, VC,

(84) **Designated States** *(unless oth kind of regional protection ava*

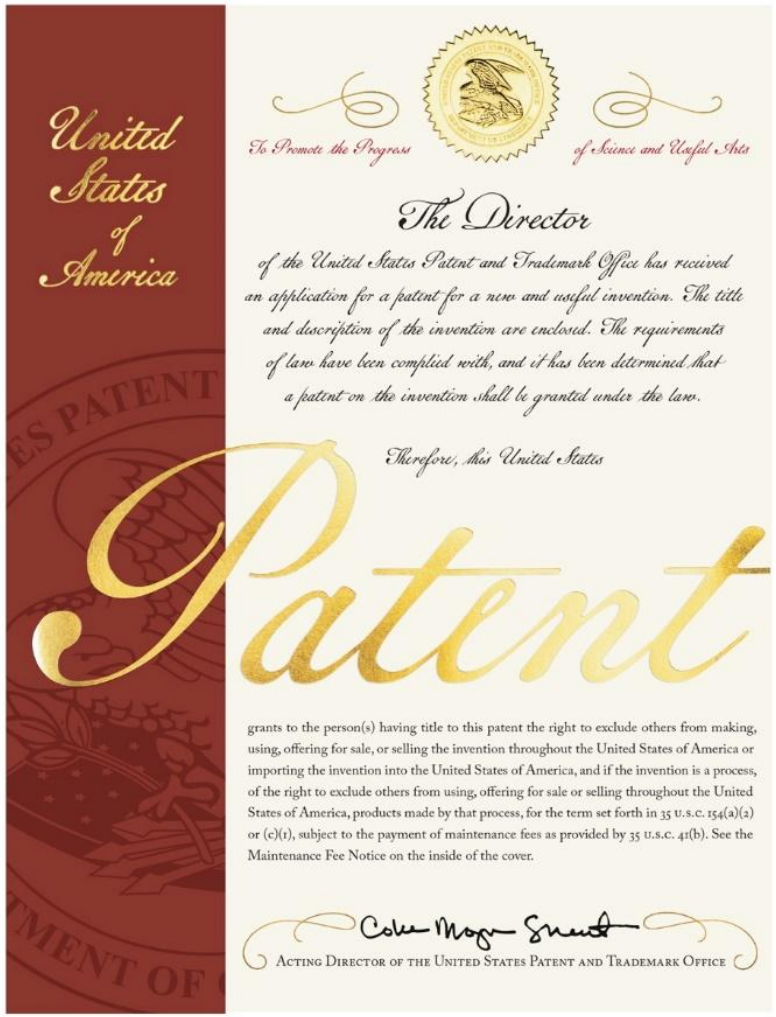
(54) **Title:** SHIELDED INTUBATION GUIDE AND METHOD

140

Fig. 1F

(57) **Abstract:** A shielded intubation guide for use in an endotracheal intubation procedure, the shielde an elongate body defining a passageway extending between a proximal opening and a distal opening of an intubation device, the shielded intubation guide being configured for insertion into a mouth of the opening is positioned proximate to the mouth and the distal opening is positioned in an airway of the sul proximal opening for substantially reducing emissions from the mouth, the shielded intubation guide allo to be performed by: inserting the blade portion of the intubation device into the passageway; position portion proximate to the larynx of the subject; and advancing an endotracheal tube along the blade por into a trachea of the subject.

Link to the patent via PATENTSCOPE



United States of America

To Promote the Progress of Science and Useful Arts

The Director

of the United States Patent and Trademark Office has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this United States

Patent

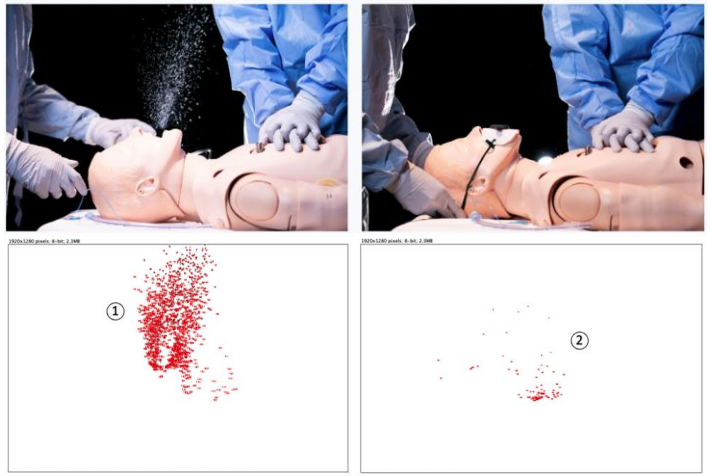
grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Acting Director of the United States Patent and Trademark Office

CLINICAL STUDIES

Pre-clinical Studies

Phase I
Aerosol Protection



10168 ± 11600 pixels *vs*. 509 ± 859 pixels; $p = 0.014$

95%

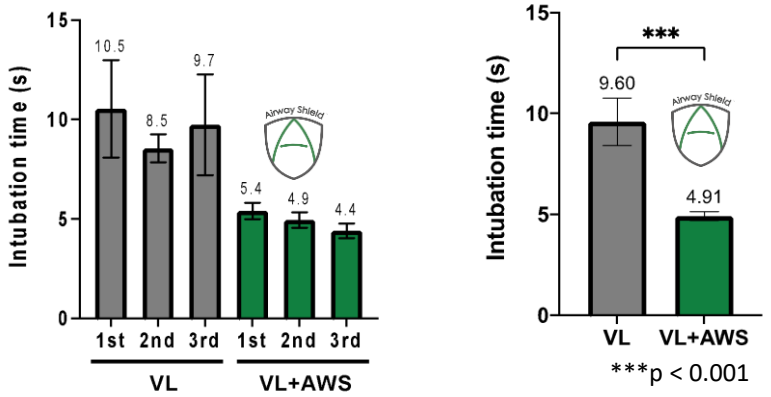
reduction in exposure to aerosols

Alonso, J. M. et al. (2022). *European Journal of Anaesthesiology*, *39*(11), 900-903 https://doi.org/10.1097/EJA.0000000000001731

CLINICIANS PROTECTED

Phase II
Feasibility of the new technique

Mean duration of each ETI attempt without & with **Airway Shield™**



50% ***Intubation time reduction***

100% ***Intubation success rate***

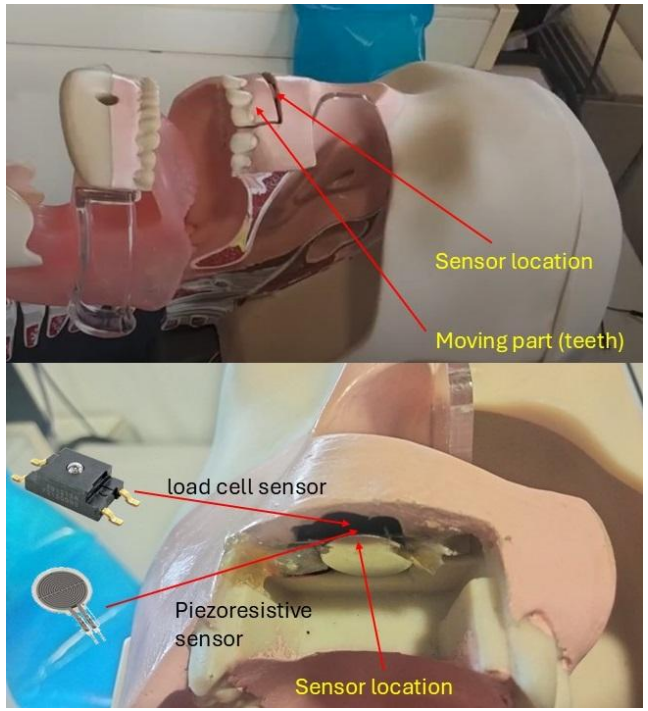
Alonso, J.M. et al. (2021). Intensive Care Medicine Experimental, 9(1), 134 (Abstract 000641). https://doi.org/10.1186/s40635-021-00413-8

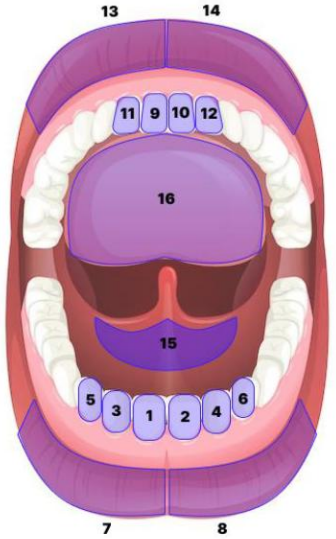
PATIENTS PROTECTED

Pre-clinical Study

Phase III – Trauma Protection

Sensorized manikin for trauma analysis during ETI: comparison between videolaryngoscopy with and without the Airway Shield™ device.





70% ***reduction in the total force applied*** *over the incisors*

50% ***Intubation time reduction***

100% ***Intubation success rate*** *(versus 80,77% Success rate without the Airway Shield™)*

PATIENTS PROTECTED

Clinical Studies

Pilot Study in OR

for safety evaluation

20 Patients

Hospital Universitario Marqués de Valdecilla. Santander, Spain

Comparative Study

vs. Traditional Technique in OR

102 Patients

Hospital Universitario de Araba. Vitoria, Spain

Airway Shield is Safe and Effective

for ETI by experience anaesthesiologist in OR

TESTIMONIALS from Anaesthesiologists involved in the Studies

Dr Ana Mendiguren

Anaesthesiologist,
Araba University Hospital, Vitoria

"Simple, intuitive and easy to use. This device facilitates intubation and protects healthcare professionals against the risk of infection".

Dr Mikel Bibanko

Anaesthesiologist,
Araba University Hospital, Vitoria

"An innovative device that will be crucial in the protection of healthcare workers".

Dr Jon Renteria

2nd year resident in Anaesthesia,
Araba University Hospital, Vitoria

"A revolutionary idea in the field of safety combined with a technology that is easy to use, even for those with less experience."

Dr Fidel de Celis

Anaesthesiologist,
Araba University Hospital, Vitoria

"Easy to use, easy to fit and easy to intubate. And at the same time protects against aerosols. Brilliant."

Clinical Studies

Spain, Italy, Sweeden, Poland, Brazil and Qatar

Multicenter Study

Comparative Study

vs. Bougie and Stylet in OR

750 Patients

GLOBAL AIRWAY MARKET

Global Airway Management Market

Globally 140,000 Hospitals & health providers

Potential Target Customers and Users of Airway Shield, including Departments of Surgery and Anaesthesia, Emergency Medicine Services, Intensive Care Units, and Pre-hospital Care and Military Services.

Intubation rate increasing due to aging population, chronic illnesses and increase of emerging respiratory diseases such as COVID-19.

3rd

most common medical procedure in hospitals

+100 Million

Intubations yearly worldwide

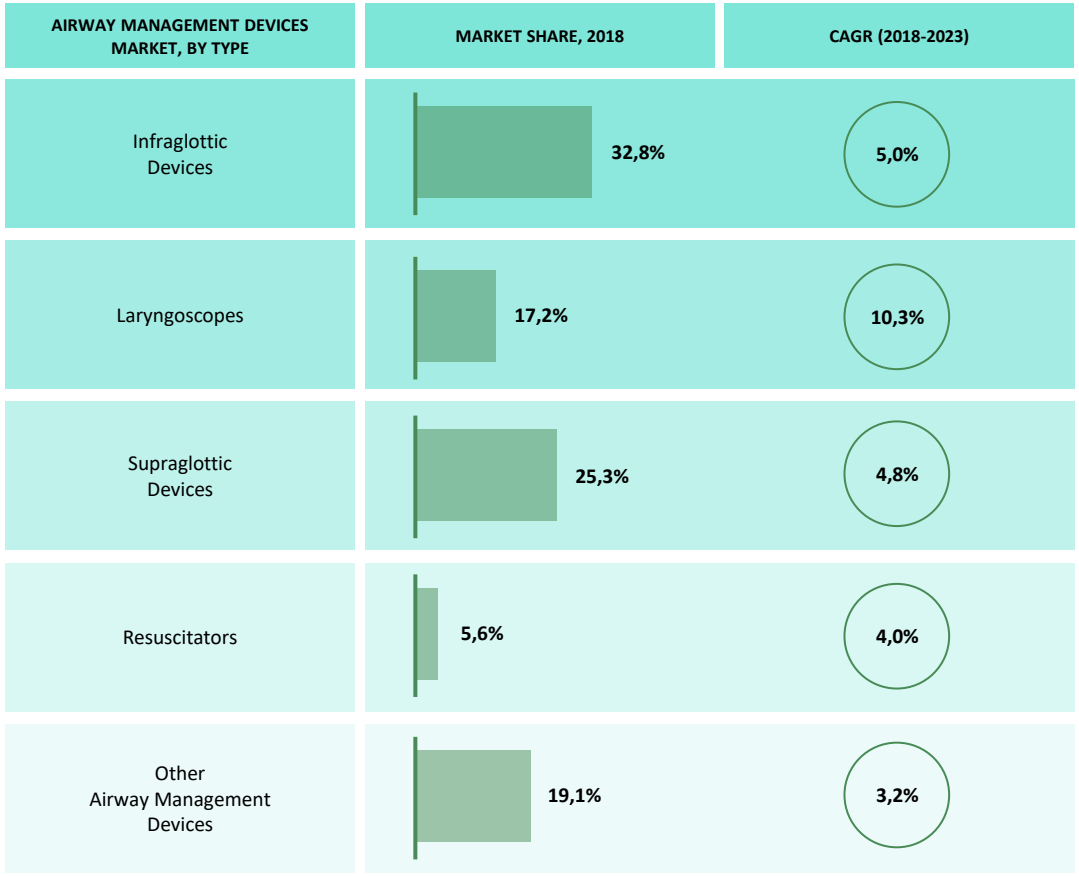
$ 2.3 Billion

Global Airway Management Market value estimation for 2025

Airway Management Market

The global airway management devices market is projected to reach USD 2.3 Billion by 2025 from an estimated USD 1.6 Billion in 2018, at a CAGR of 5.6%.

The airway management devices market segmented by type



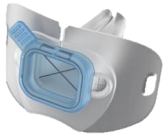
Airway Shield is the disruptive medical device that will replace all devices used when endotracheal intubation is difficult. This is the case of supraglottic, resuscitation and other devices, which represent 50% of the market share and were born as a response to the difficulty of the endotracheal intubation procedure

The Airway Shield is the ultimate complementary device to be used for all endotracheal intubations

Competing for 50% of the Global Airway Management Market

COMPETITORS

Direct Competitors

	Airway Shield™	Bougie	Stylet
			
Price	10 €	16 €	4 €
Easy of use	Designed for **easy use**, even by less experienced practitioners, reducing the skill barrier. *(Alonso, JM. et al., 2022).*	Simple to handle but **requires skills** for optimal performance *(Jaber et al., 2021).*	**Requires advanced technique** to properly shape and maneuver *(Tollman & Ahmed, 2022).*
Time efficiency	**50% reduction** in intubation time *(Alonso, JM. et al., 2022)*	Increases time	Increases time
Safety	**Protects** patients' oral mucosa and teeth from trauma and protects clinicians from respiratory aerosols, reducing complications and infection risks. *(Alonso, JM. et al., 2021).*	**Risk of airway trauma**, including airway perforation, haemorrhage, and bronchoalveolar injury *(Arndt et al., 2008; Grape & Schoettker, 2017).*	**Risk of trauma**, accidental extubation, and other complications like stylet breakage. *(Gray et al., 2018; Chalhoub et al., 2013).*

TEAM

Airway Shield Team

Airway Shield Team combines a deep expertise in the medical field with a solid knowledge and experience in quality, commercialization and business development.

Dr. Julio Alonso, M.D.

Founder and CEO

Internationally recognised Intensive Care Specialist since 2011, with an extensive expertise in airway management and the development of new medical devices

Cambell Smith

CPO

With 20+ years in industrial design, founder of Metric Studio, expert in CAD/CAM/CAE and product development, leading Airway Shield's 3D design.

Jose Luis Martín, MBA.

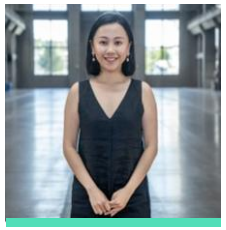
CFO

With extensive experience in biotech, venture capital, and finance. Professor at ICADE and startup mentor.

Natalia Moracho, Ph.D.

Director of Medical Communication

PhD in Health Sciences and specialized in Clinical Research. 6 years of extensive scientific background, with several journal publications and MSc in pharmaceutical industry.



Joanne Zusieh, MBA.

Director of Business Development

Specialist in transition of innovative MedTech from research to commercialization. Background in go-to-market strategy and global commercialization collaborations since 2018

Carlota Muñoz, MSc.

Director of Quality and Regulatory Department

Experienced in Quality Assurance, supplier coordination and scientific research with 4 years experience in Basic Science and quality technician.

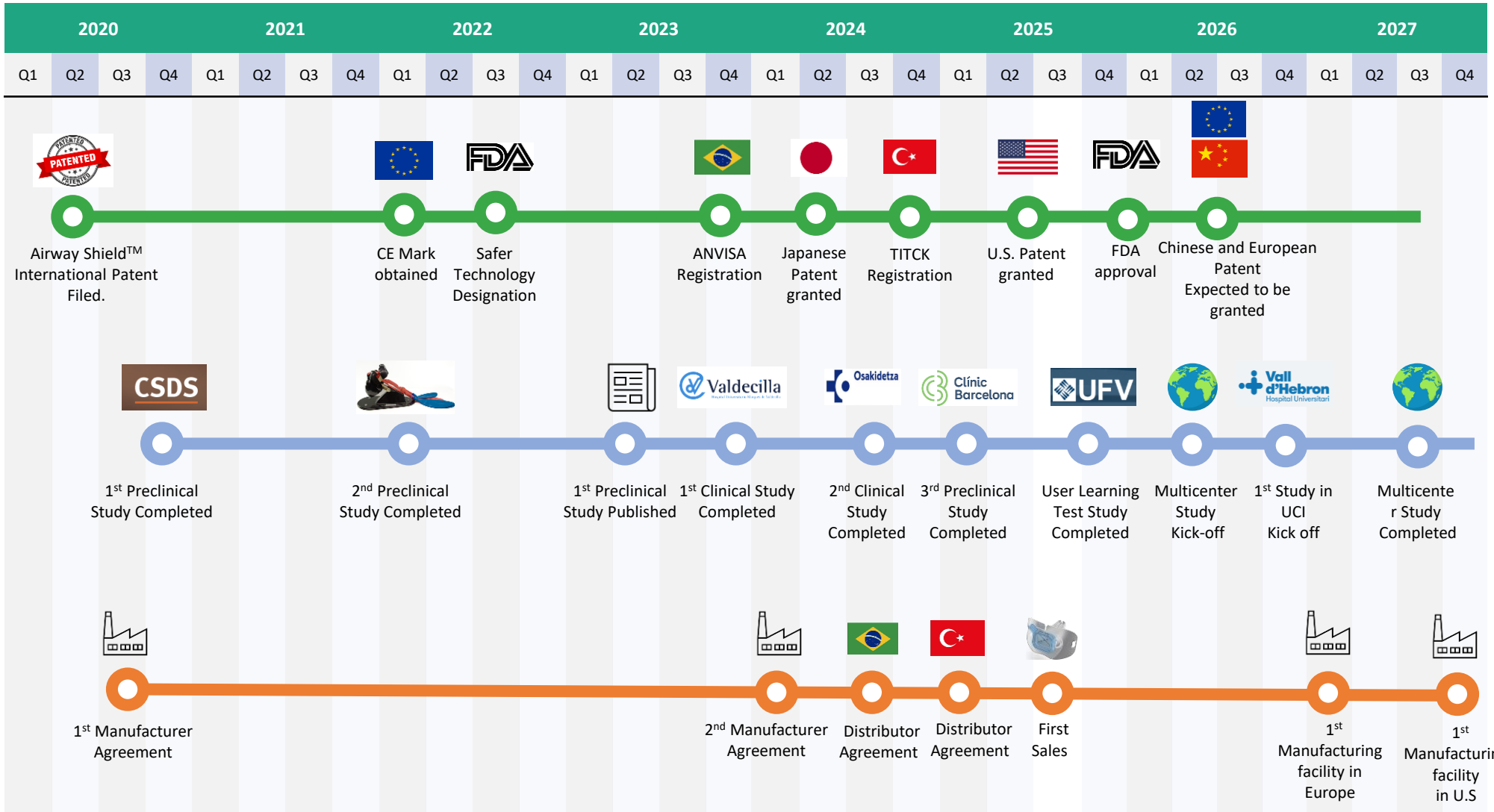
Nieves Espinosa

Director of Business Management

Strong background in Corporate Journalism, specialized in communication strategy with hospitals and KOLs

MILESTONES AND FUNDING

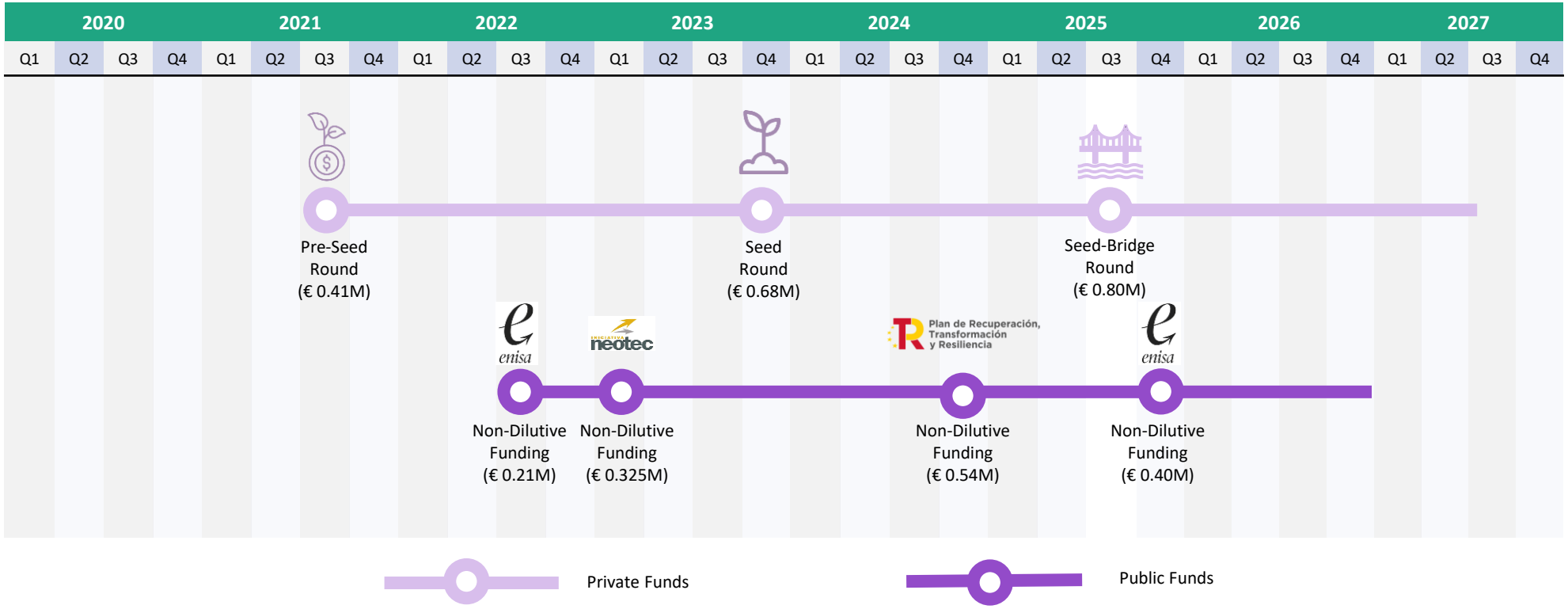
Achieved and near future milestones



Achieved and near future milestones

Public and Private Funds

June 2020 - December 2027



Validations

Public institutions trusted on us

Awards

Winners Cantabria 2022

Global Winners 2023

Global Winners 2024

Validations

Entrepreneur Events

IV Al-Andalus Innovation Venture Edition (Seville, Spain)

X B-Venture Edition (Bilbao, Spain)

4YFN (Bcn, Spain)

Acceleration Programs

Healthtech 2023 Program (Boston, US)

AceleraStartup 2024 Program

S2B Health&Care 2024 Program

Lanzadera 2025 Program

Recognitions

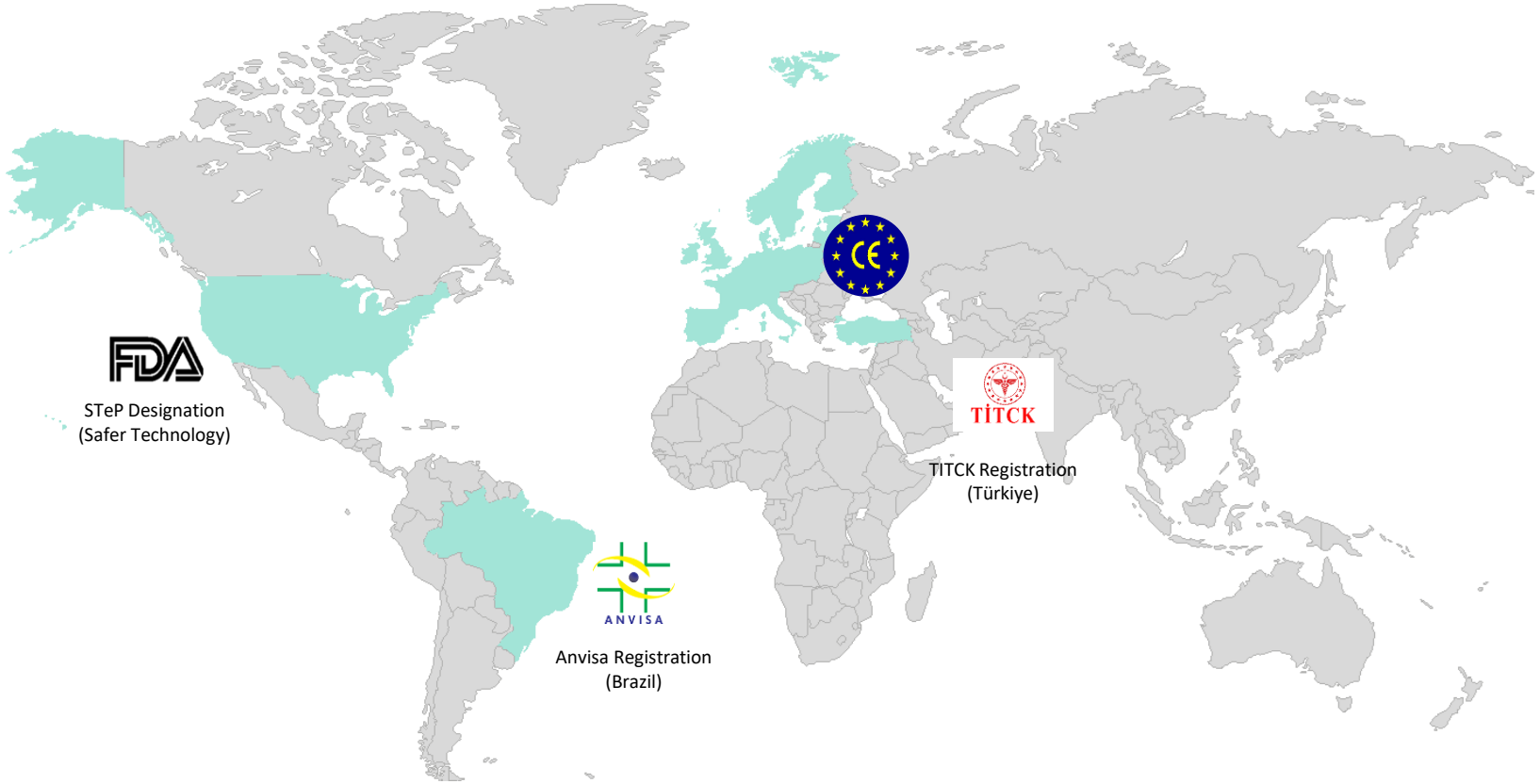
Safer Technology (2023)

BioExpert Network (2023)

GO-TO-MARKET AND REGULATORY

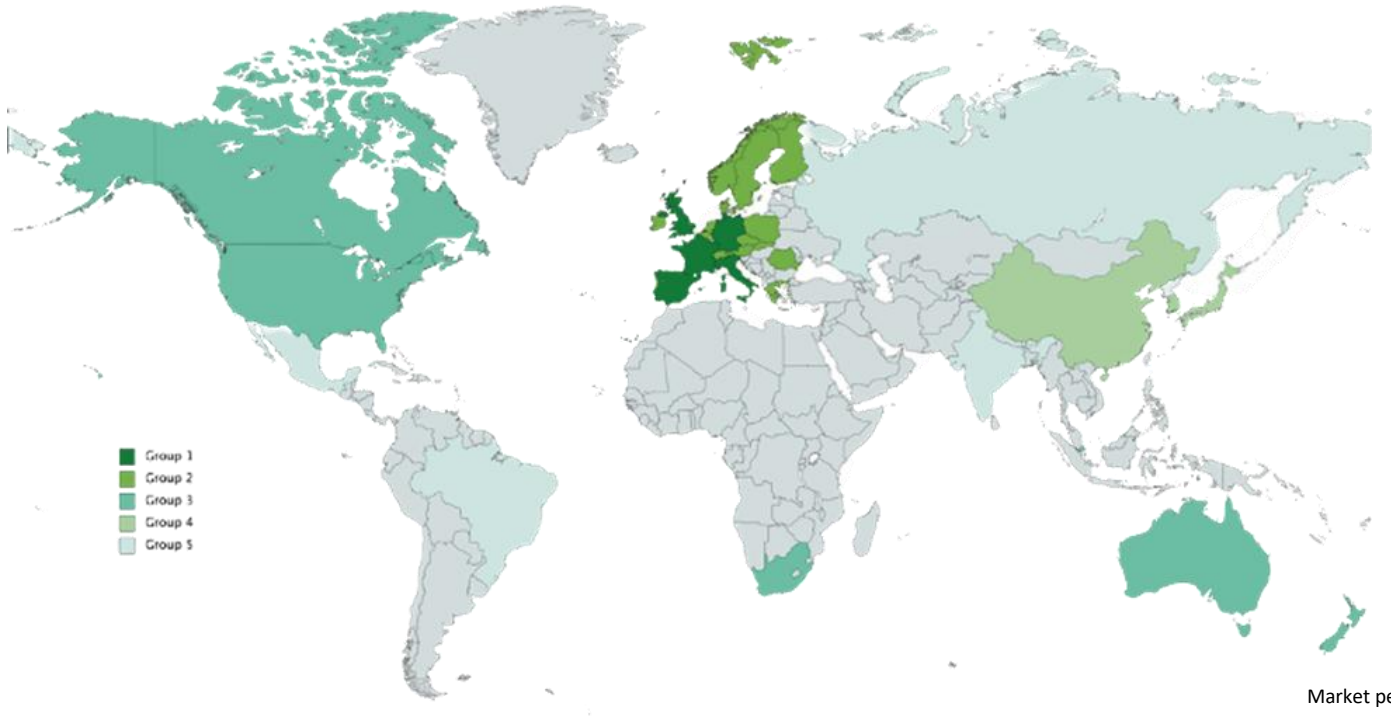
Regulatory Achievements

Airway Shield™ is a device with CE Mark, ready for commercialization in Europe



Airway Shield™ has received the designation of "**Safer Technology**" by the FDA, which will facilitate the commercialization in US

Go-to-Market Strategy



Estimated Number of Intubations per group of countries*

GROUP 1	5.5M / yr
GROUP 2	2.9M / yr
GROUP 3	7.7M / yr
GROUP 4	27M / yr
GROUP 5	31.2M / yr

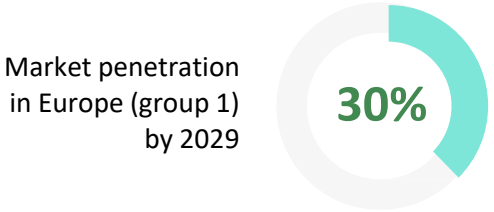
Estimated market penetration in each group of countries over the next 5 years

	2025	2026	2027	2028	2029
Market penetration in Group **1**	**0,1%**	**0,5%**	**1,5%**	**10%**	**30%**
Market penetration in Group **2**			**0,7%**	**5%**	**27%**
Market penetration in Group **3**			**0,2%**	**3%**	**18%**
Market penetration in Group **4**				**0,3%**	**7%**
Market penetration in Group **5**					**0,3%**

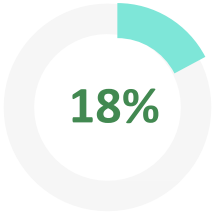
*According to the 4th National Audit Project, 1.1 million ETI procedures are performed per year in the UK. The total population in UK is 66 million. We extrapolate this proportion to the other countries to obtain the estimate of intubation per year in each country and groups of countries. It is a conservative estimation (based on numbers from 2013).

Market: Financial Projection

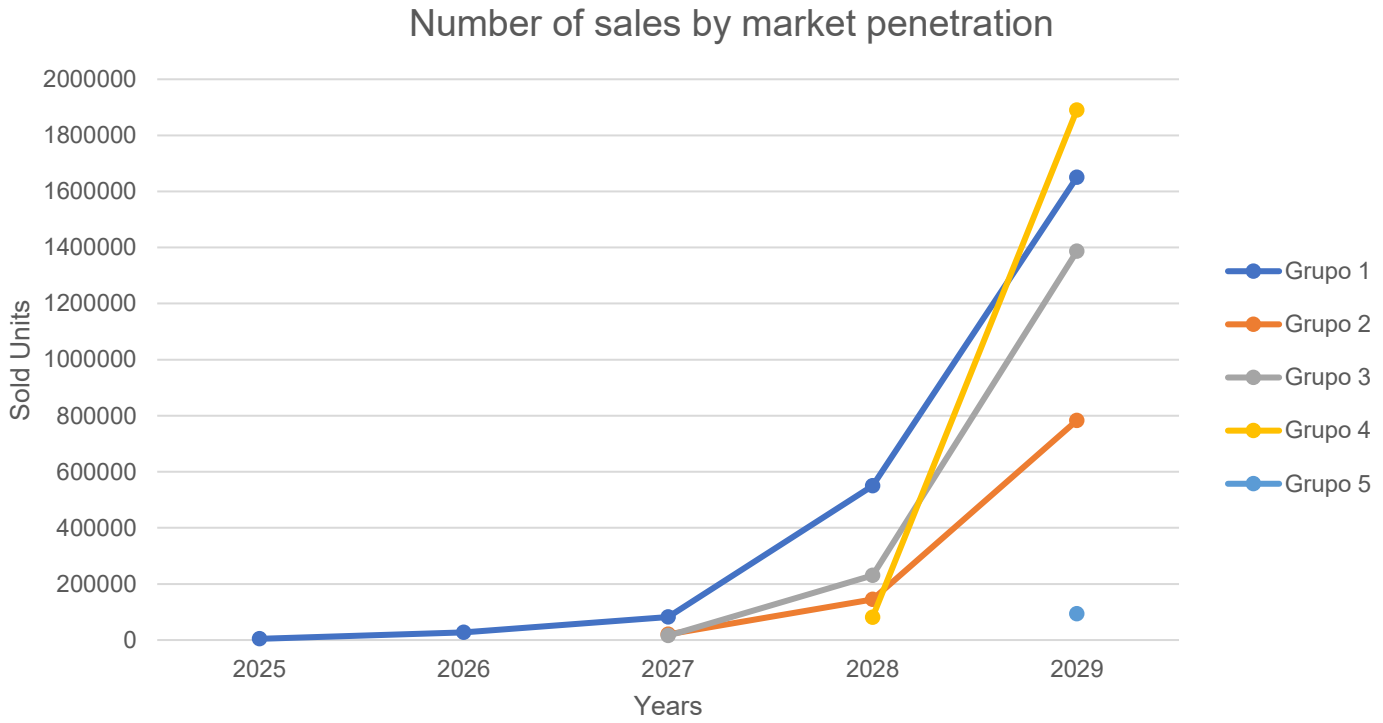
We will achieve 30% market penetration in Western Europe and 18% market penetration in USA by 2029.



Market penetration in Europe (group 1) by 2029



Market penetration in USA by 2029

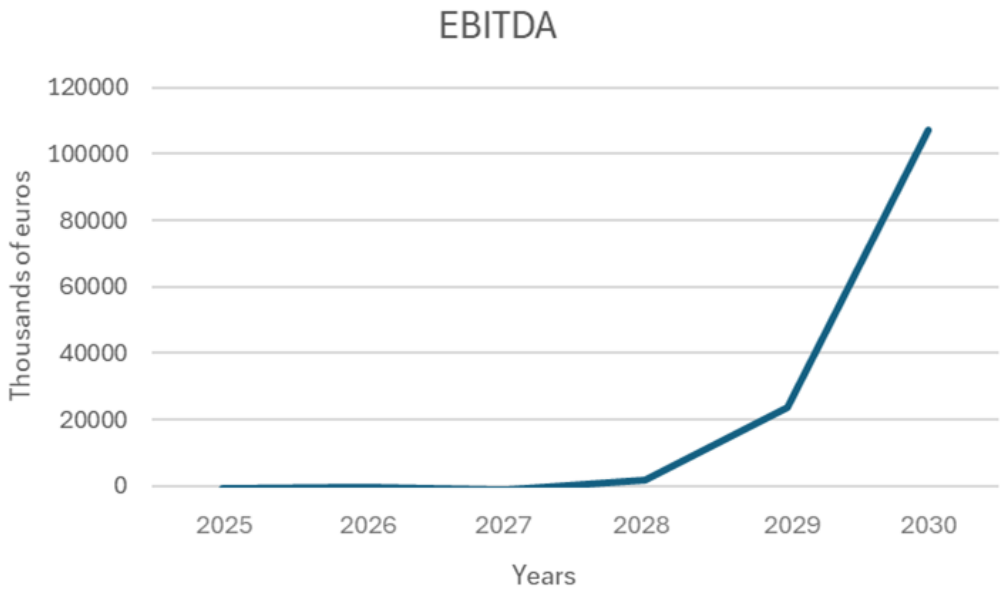


€38M **Worldwide sales by 2029**

Market: Financial Projection

We will achieve positive EBITDA and Cash Flow by 2028.

Figures in thousands of euros	2025	2026	2027	2028	2029	2030
Revenues	42,0	189,0	758,7	6.439,2	39.039,6	165.684,1
Expenses	836,0	500,4	1.689,2	2.440,4	3.861,5	10.019,4
EBITDA	-532,9	-96,4	-1.148,3	2.038,6	23.534,5	107.149,7



Future Roadmap

	2026	2027	2028	2029	2030
Q1	FDA approval Recurrent sales in Spain & Portugal	New Manufacturing facility in Europe New devices ready for regulatory process		Market Launch in the rest of the world	
Q2	Market launch in Europe, rest of Big 5 (DE, UK, IT and FR)	Recurrent sales in Europe 1st sales in U.S Multicenter study completed	Recurrent sales in U.S		Global distribution
Q3		Open Subsidiary in Hong Kong			
Q4	Open Subsidiary in U.S. Market launch in U.S.	Market launch in Asia New Manufacturing facility in U.S.		Continue exponential growth	

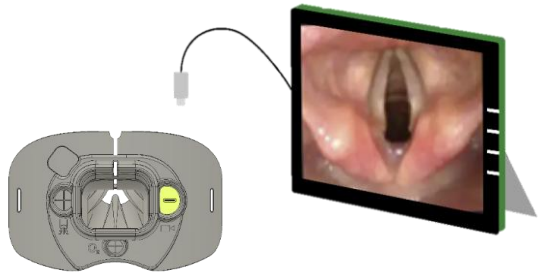
New Developments

Pedriatic sizes

Actual device's size

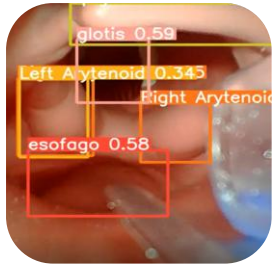
New pediatric sizes

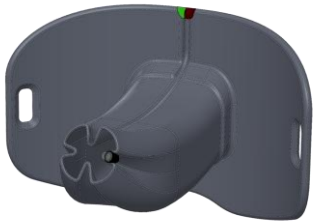
Video Airway Shield™



An advanced version of the AWS™ that integrates video capabilities, allowing its use with direct vision laryngoscope and making it accessible in any department, even in the absence of a video laryngoscope.

Airway Shield™ + AI





In combination with our own image recognition software, it will allow to recognize anatomical structures of the airway and thus, confirm the correct placement of the endotracheal tube in real-time.

Video-AWS-Scope™

This new development takes the Video- AWS™ a step further by providing the ability to direct the ETT without the need for a laryngoscope or videolaryngoscope, making its use universal and independent of complementary devices. It will reduce costs and increase accessibility in healthcare systems.

As we are **currently working in the IP protection for some of these developments,** we cannot offer more details of their new features and advantages.

NEW FUNDING ROUND

Funding Rounds

FFF Round via Capital Cell in September 2021

415.000 € raised in less than 24 hours
Post-money valuation: 2.015.000€

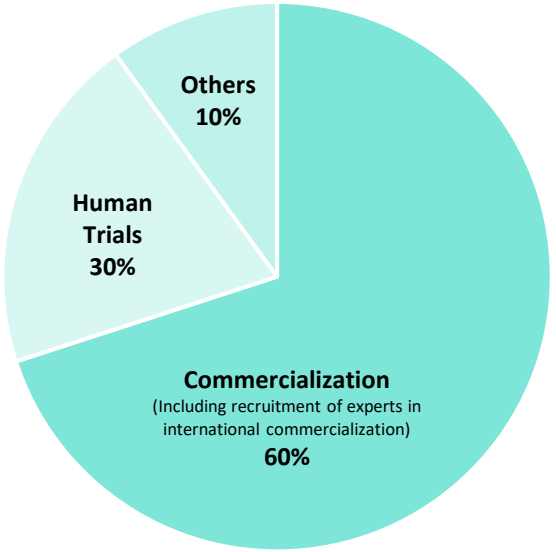
Pre-Seed Round via Capital Cell in December 2023

680.000 € raised in less than 10 days
Post-money valuation: 4.680.000€

Seed-Bridge Round 2025

✓ **Q3 2025**

✓ Objective:
Raise **800.000 €**



30% Human trials:

- Cost-effectiveness
- Multicenter International Study

60% Commercialization

- USA Market Access Studies
- Sales network expansion
- Marketing promotional

EXIT STRATEGY

Exit Strategy

Our exit strategy is an acquisition by a "**major player**" in 2028, or

an initial public offering (IPO) for listing on a public market such as Euronext

POTENTIAL BUYERS

are big players in the airway management market

flexicare

a su lado VYGON

INTERSURGICAL COMPLETE RESPIRATORY SYSTEMS

Armstrong Medical

BD

smith&nephew

Ambu

STORZ KARL STORZ—ENDOSKOPE

Medtronic

VERATHON

Comparable operations

2012

Teleflex®

Acquires
all assets of
LMA International N.V.

$ 276M

LMA® Supreme™ Airway

2013

Ambu

Acquires
all assets of
King Systems Inc.

$ 120M

KingVision® Video Laryngoscope

2015

Medtronic

Acquires
all assets of
Aircraft Medical L.T.D.

$ 110M

McGRATH® MAC Video Laryngoscope

Our Dream,
to make intubation safe everywhere
and save thousands of lives…

… we will reach a Global Impact.

Airway Shield™

Safer Intubation