
ADVANCE
The Safest Glove

The challenge

What if...

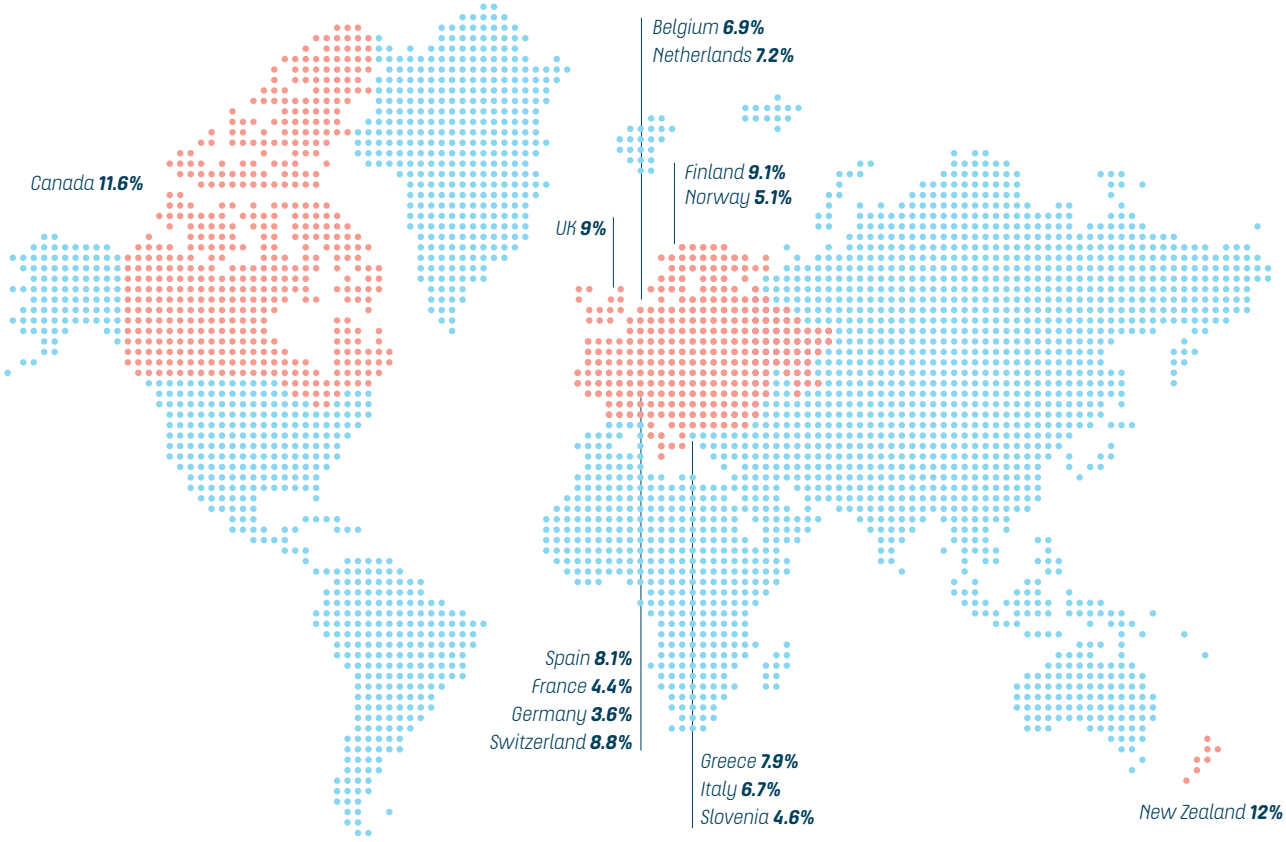
We could assist healthcare professionals in their endeavours to prevent thousands of deaths each year?

Healthcare-associated infections.
Why do they matter?

Healthcare-associated infections (HCAI) are acquired while patients are receiving treatment for medical or surgical conditions, and are the most frequent adverse event during care delivery.[1]

Pooled HCAI prevalence in mixed populations was 7.6% in high-income countries.[1]

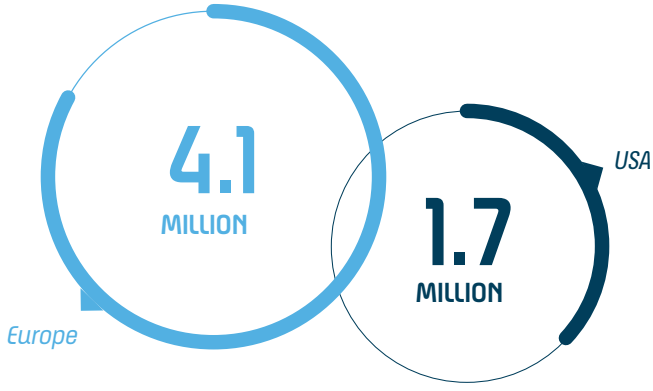
Prevalence of health care-associated infection in high-income countries, 1995-2010*[*1]



**For countries with more than one study, the most recent figures are included.*

1. *World Health Organization. Report on the Burden of Endemic Health Care-Associated Infection Worldwide. 2011.*

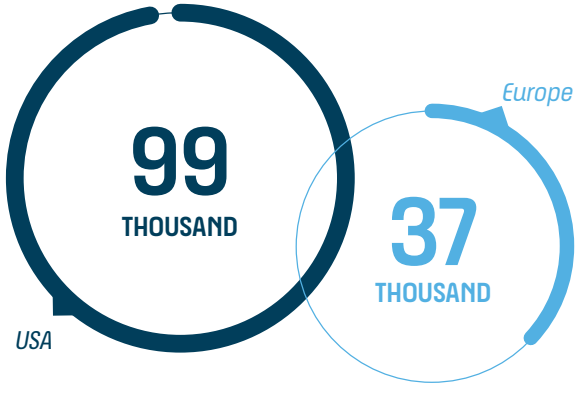
Number of patients affected by HCAI per year



4,5% INCIDENCE RATE IN THE USA

16 MILLION EXTRA-DAYS OF HOSPITAL STAY IN EUROPE

Number of deaths caused by HCAI



HCAI is also associated with many other negative outcomes, such as:

- *Prolonged hospital stay*
- *Long-term disability*
- *Increased resistance of microorganisms to antimicrobials*[1]

HCAI is defined as: "An infection occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission. This includes infections acquired in the hospital, but appearing after discharge, and occupational infections among staff of the facility".[2]

The use of single-use nonsterile gloves in the hospital setting is second only to proper hand washing in reducing contamination during patient contact.[3]

To avoid the spread of HCAI, gloves are an essential tool for healthcare professionals.

1. World Health Organization. Report on the Burden of Endemic Health Care-Associated Infection Worldwide. 2011. **2.** Berthelot P, et al. Bacterial contamination of nonsterile disposable gloves before use. Am J Infect Control. 2006;34(3):128-30. **3.** Moran V, Heuertz R. Cross Contamination: Are Hospital Gloves Reservoirs for Nosocomial Infections?. Hosp Top. 2017;95(3):57-62.

What if...

we could support healthcare professionals in reducing the social and economic impact of infections?

The economic burden of sepsis

In addition to the impact they have on health, infections also translate into a massive additional financial burden for health systems and high costs for patients and their families.

Annual economic impact of HCAI

US$ 6.5 BILLION[1]

€ 7 BILLION[1]

Septisis

Sepsis is a life-threatening syndrome of organ dysfunction caused by a dysregulated host-response to an infection.

Sepsis recognition and management is a major challenge for healthcare systems worldwide. ***Sepsis affects hundreds of millions of patients worldwide every year.***[2]

Sepsis represents a substantial economic burden.[2]

Costs per capita (median)

SPAIN (2012) - **71€**

UK (2015) **- 43€**

USA (2020) - **39€**

ITALY (2011) - **147€**

1. *World Health Organization. Report on the Burden of Endemic Health Care-Associated Infection Worldwide. 2011.* ***2.*** *Van den Berg M, et al. Hospital-related costs of sepsis around the world: A systematic review exploring the economic burden of sepsis. J Crit Ca*

The social burden of sepsis

Nearly a quarter to a third of people with sepsis had a healthcare visit the week before being hospitalized.[1]

To avoid the spread of healthcare-associated infections, ***gloves are an essential tool for healthcare professionals.***[2]

Healthcare professionals can effectively reduce the risk of cross-contamination and alleviate the social and economic burden of sepsis and HCAI by utilizing the mos appropriate gloves in their procedures, according to the WHO guidelines.

Over 24% of patients affected by healthcare-associated sepsis and

52.3% of those patients treated in an intensive care unit die each year worldwide![2]

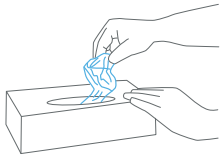
1. *Centers for Disease Control and Prevention. What is Sepsis? Available at: https://www.cdc.gov/sepsis/what-is-sepsis.html.* **2.** *Moran V, Heuertz R. Cross Contamination: Are Hospital Gloves Reservoirs for Nosocomial Infections?. Hosp Top. 2017;95(3):57-62. re. 2022;71:154096.*

WHO glove information leaflet (2009) [1]

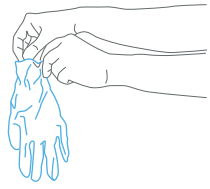
Technique for donning and removing non-sterile examination gloves

When the hand hygiene indication occurs before a contact requiring glove use, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water.

How to don gloves

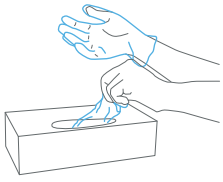


1. Take out a glove from its ***original box.***

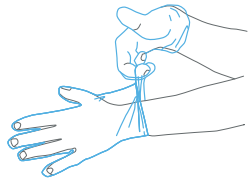


2. Touch only a ***restricted surface of the glove corresponding to the wrist*** *(at the top edge of the cuff).*

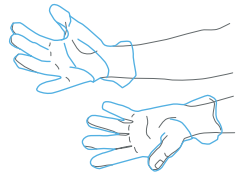
3. Don the first glove.



4. Take the second glove with the bare hand and ***touch only a restricted surface of glove corresponding to the wrist.***

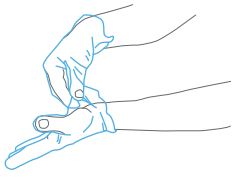


5. To avoid touching the skin of the forearm with the gloved hand, ***turn the external surface of the glove to be donned on the folded fingers of the gloved hand,*** *thus permiting to glove the second hand.*

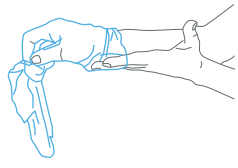


6. Once gloved, hands should not touch anything else *that is not defined by indications and conditions for the glove use.*

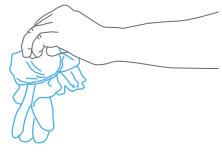
How to remove gloves



1. Pinch one glove at the wrist level to remove it, *without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out.*



2. Hold the removed glove in the gloved hand and ***slide the fingers of the ungloved hand inside between the glove and the wrist****. Remove the second glove by roling it down the hand and fold into the first glove.*



3. Discard the removed gloves.

The WHO – World Health Organization recommends putting gloves on by the cuff.

1. *World Health Organization. Glove Information Leaflet. 2009.*

ADVANCE
The Safest Glove

Innovative approach

MADE IN EUROPE

What if...

Gloves had their first real breakthrough since the 1960s?

Since the 1960's, everything changed, but gloves didn't. Does this make sense?

*Though **gloves are the most used Personal Protective Equipment** (PPE)/Medical Device and represent **one of the most important ways to prevent healthcare-associated infections**, they haven't evolved much in the last decades.*

The evolution of the single-use glove has only been related to the raw materials used.

RACLAC decided to completely change the initial concept of single-use, nonsterile gloves, based on questions such as:

- *Why do **healthcare professionals use gloves with a high percentage of defects?***
- *If conventional gloves are not produced in a controlled environment, **can they be considered safe and clean?***
- *Does it make sense to believe that a **medical device packed in a cardboard box** (porous material) **that travels in containers on ships for about 2 months before reaching its destination** is safe to use on healthcare professionals and patients?*
- *How can we **trust packaging that is not airtight before being opened** and cannot be cleaned on the outside when touching potentially contaminated surfaces?*
- *Why can't professionals **remove gloves from the packaging by the cuff,** as recommended by the WHO since 2009?*[1]

1. World Health Organization. Glove Information Leaflet. 2009.

RACLAC's mission:
#protectingpeople

"We work diligently every day, driven by our mission to ***protect people.***

Our unwavering commitment to ***innovation*** *allows us to develop* ***cutting-edge solutions*** *that safeguard individuals and communities.*

Through our relentless pursuit of ***excellence****, we are dedicated to creating a* ***safer world*** *for all."*

Pedro Miguel Costa, CEO & Founder

A journey of innovation

2016

Kick off

2018

Validation of the production concept in pilot project

1st factory in Europe *to manufacture examination gloves*

2022

Launch of the ***R.ADVANCE: The Safest Glove***

2023

Launch of the ***R.DISPENSER***

SOON

Launch of the ***R.PICK***

What if...

we could improve healthcare professionals and patients' safety by inspecting each glove?

R.ADVANCE: the safest glove

An individual inspection to 100% of the gloves produced

To RACLAC, protection goes beyond the norm!

We have developed a fully automated production line, which allows for quality control, in different steps, of 100% of the gloves produced. By carefully examining each glove, we are able to identify non-compliant gloves and remove them, which allows us to achieve an ***unprecedented level of confidence in the protection of HCPs and Patients.***

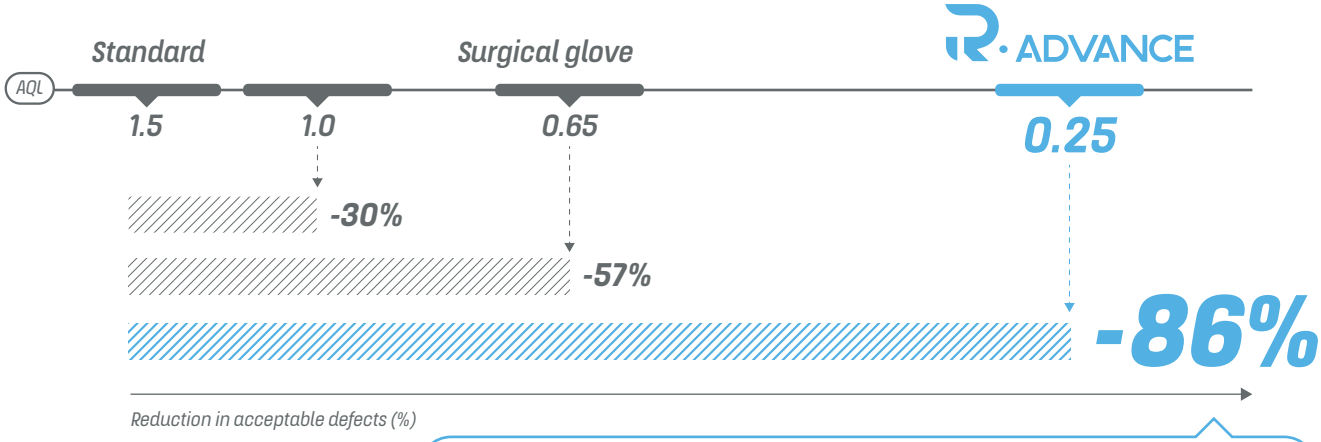
R.ADVANCE: the safest glove - AQL 0.25

*AQL stands for Acceptance Quality Limit, which serves as an **indicator of the safety and quality of gloves**, reflecting the maximum level of defects that are acceptable.*

***The lower the AQL, the safer the glove is**, as it is used to assess freedom from holes, under the EN 455-1:2020 standard.*

R.ADVANCE sets new protection levels

Comparative interpretation of defects in the different AQLs according to the AQL scale[1]



R.ADVANCE reduces the risk of defects (punctures and micro-punctures) in -86% vs the standard AQL (1,5) mentioned in EN 455-1:2020 and standard in the market, to healthcare procedures.

Some of the most prevalent microorganisms in healthcare-associated infections can pass through a microhole that is invisible to human eyes and can be in touch with our skin.
To address this potential risk, RACLAC has reached an unparalleled AQL value of 0.25, which is the result of inspecting 100% of the gloves and removing the non-conforming gloves detected.

1.Comparative interpretation of defects across different AQLs according to the AQL scale governed by the EN 455-1:2020 standard, for a batch of 150,000 gloves produced with a sampling of 200 units.

R.ADVANCE: The safest glove

How is the AQL value determined?

Following norm ISO 2859, for an example batch of 4 million gloves, 500 random gloves are analyzed:

	AQL	Nro. of defective gloves allowed in the sample	Nro. of defective gloves per batch	% of defective gloves per batch
Examination gloves	AQL 1.5	14	112 000	2.8%
	AQL 1.0	10	80 000	2%
Surgical gloves	AQL 0.65	7	56 000	1.4%
R. ADVANCE	**AQL 0.25**	**3**	**24 000**	**0.6%**

But RACLAC doesn't just analyse the 500 gloves in each batch.

We are the first company in the world to inspect 100% of the gloves manufactured. And every time we detect a defective glove, we remove it - that's how we achieved an unparalleled AQL of 0.25.

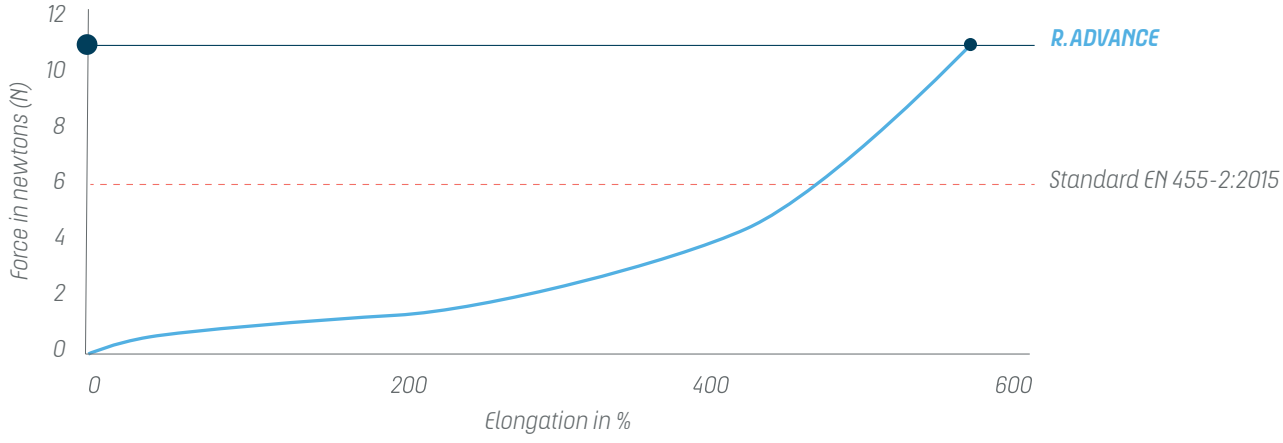
We believe that an undetected puncture can put a professional and/or patient at risk.

The lowest AQL = Minimization of HCAI.

The highest elasticity and resistance

R.ADVANCE present the highest levels of strength, safety and premium elasticity, *decreasing occupational hazards due to their high puncture resistance and ensuring much longer durability and ability to withstand prolonged use in challenging working conditions.*

Resistance of R.ADVANCE vs. STANDARD gloves in healthcare



R.ADVANCE gloves can withstand ***almost double the force (between 10 newtons to 12 newtons) until they tear*** *compared to the standard required by EN 455 (≥6 newtons).*

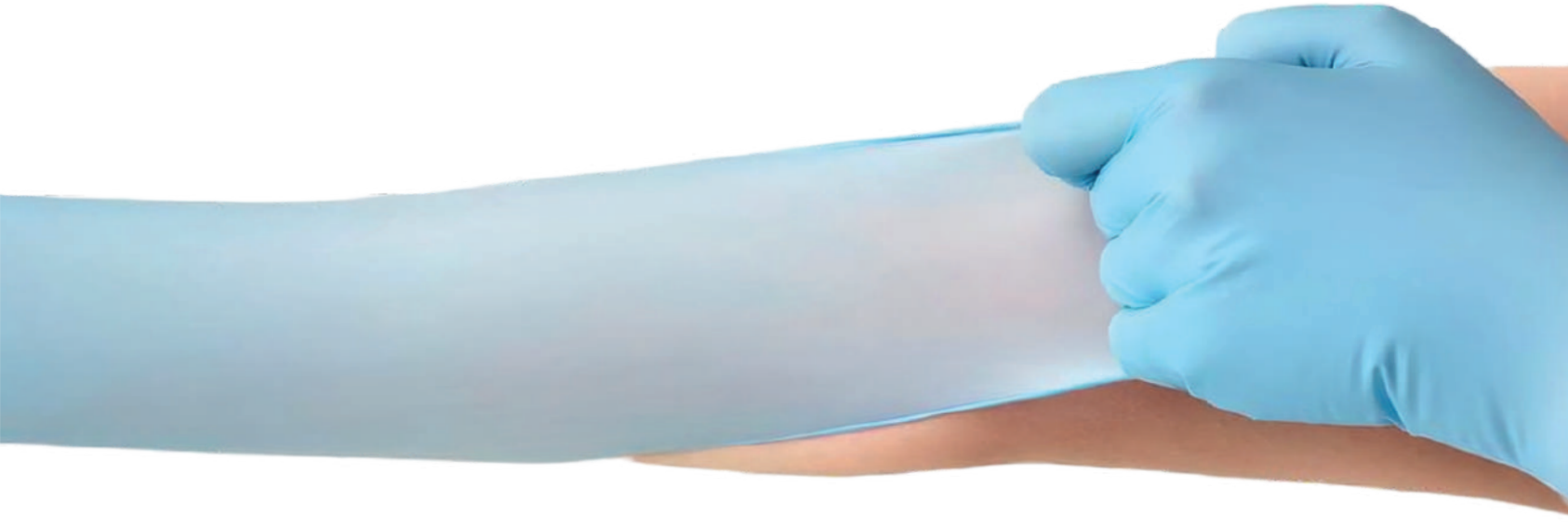
R.ADVANCE benefits from two unique and innovative formulations

R.TECHpure.02

- Greater resistance when putting the glove on, due to its reinforced edge
- High puncture resistance
- Premium elasticity
- Longer lifespan
- Higher protection
- Time and waste saving

R.SLIP

- Easier and faster donning
- Improved usage comfort
- Less hand fatigue during procedures
- Reinforced edge
- Sensitivity like a second skin



R.ADVANCE: the purest glove

Evidence shows that disposable gloves are already contaminated *with a large variety of spore-forming and non-spore-forming bacteria* ***when they reach the hands of professionals.***[1]

Determination of a population of microorganisms (bioburden)[2]

Conventional gloves

Assay	Aerobic bacteria (CFU/sample)	Fungi/yeast (CFU/sample)	Anaerobic bacteria (CFU/sample)	Total bioburden (CFU/sample)
Assay #1	9	5	4	**18**
Assay #2	12	2	5	**19**
Assay #3	3	10	3	**16**
Assay #4	5	17	4	**26**
Assay #5	2	4	6	**12**
Assay #6	5	15	8	**28**
Assay #7	3	2	7	**12**
Assay #8	2	7	5	**14**
Assay #9	1	9	9	**19**
Assay #10	2	10	5	**17**

CFU: *colony forming uni*

Adapted from Raimundo J, Oliveira A. Labfit.Imp.85_Technical Report (Edition5). Labfit-HPRD. 2023.

1. *Berthelot P, et al. Bacterial contamination of nonsterile disposable gloves before use. Am J Infect Control. 2006;34(3):128-30.* **2.** *Raimundo J, Oliveira A. Labfit.Imp.85_Technical Report (Edition5). Labfit-HPRD. 2023.*

*The R.ADVANCE gloves are produced in a **unique and innovative 100% automated line** and in a **controlled environment** with HEPA filters, **without human intervention**. They are packed in an air and watertight flowpack, from production to the HCP, keeping them pure until they are used in a clinical environment. These are **highly pure nonsterile gloves**, a tool for controlling cross-contamination and bioburden.*

Determination of a population of microorganisms (bioburden)[1]

	R.ADVANCE			
Assay	*Aerobic bacteria (CFU/sample)*	*Fungi/yeast (CFU/sample)*	*Anaerobic bacteria (CFU/sample)*	*Total bioburden (CFU/sample)*
Assay #1	*<1 (LOQ)*	*<1 (LOQ)*	*<1 (LOQ)*	**<3**
Assay #2	*<1 (LOQ)*	*<1 (LOQ)*	*2*	**<4**
Assay #3	*2*	*<1 (LOQ)*	*2*	**<5**
Assay #4	*2*	*<1 (LOQ)*	*<1 (LOQ)*	**<4**
Assay #5	*<1 (LOQ)*	*<1 (LOQ)*	*<1 (LOQ)*	**<3**
Assay #6	*1*	*<1 (LOQ)*	*1*	**<3**
Assay #7	*<1 (LOQ)*	*<1 (LOQ)*	*<1 (LOQ)*	**<3**
Assay #8	*<1 (LOQ)*	*1*	*2*	**<4**
Assay #9	*<1 (LOQ)*	*<1 (LOQ)*	*2*	**<4**
Assay#10	*<1 (LOQ)*	*<1 (LOQ)*	*3*	**<5**

***CFU:** colony forming uni; **LOQ:** limit of quantification*

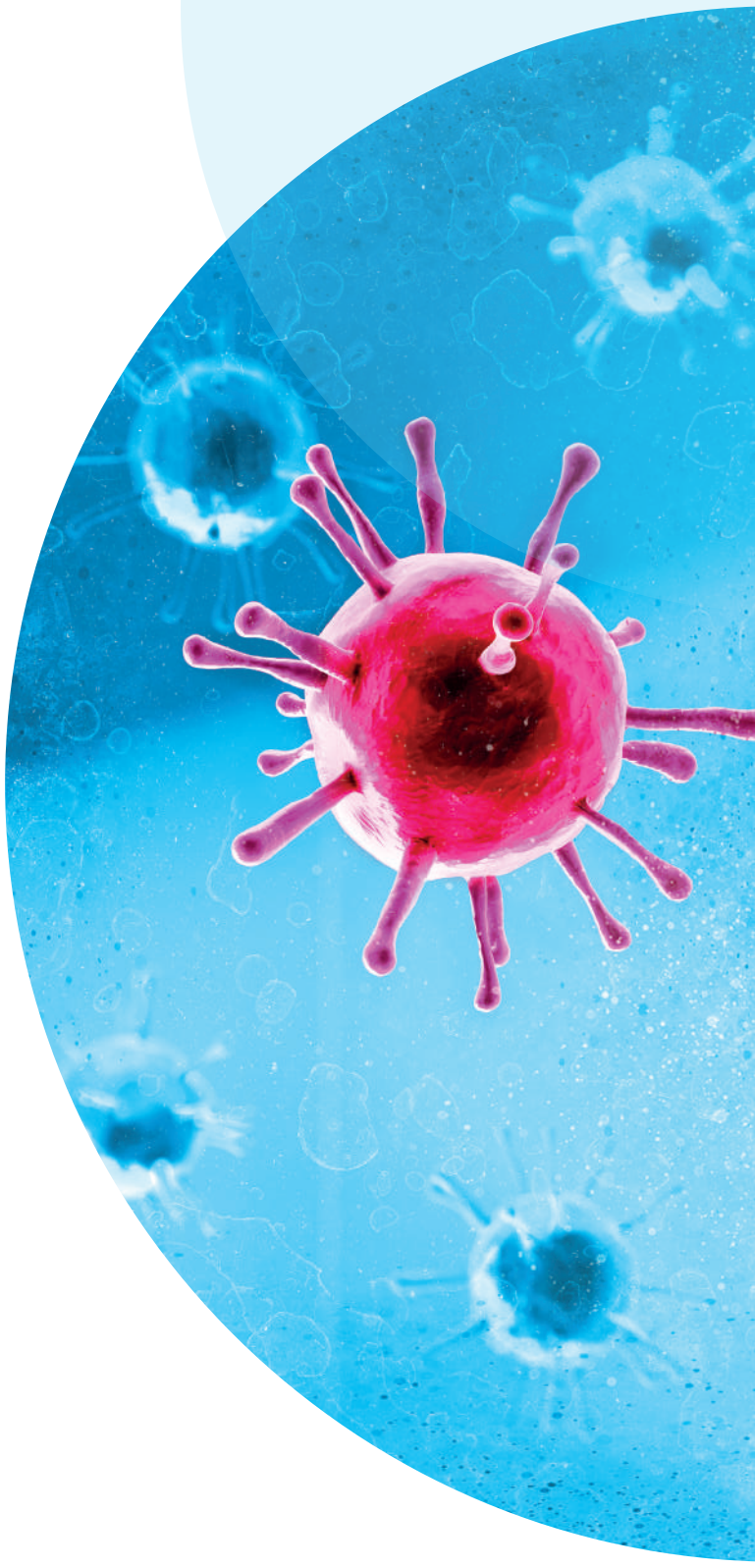
Adapted from Raimundo J, Oliveira A. Labfit.Imp.85_Technical Report (Edition5). Labfit-HPRD. 2023.

*There is a **drastic reduction of the contamination in R.ADVANCE gloves** compared to the high microbiological burden present in conventional glove boxes.*

1. *Raimundo J, Oliveira A. Labfit.Imp.85_Technical Report (Edition5). Labfit-HPRD. 2023.*

What if...

There was an innovative flowpack that protected gloves and allowed HCPs to follow WHO guidelines?



A unique and innovative flowpack designed to reduce the risk of cross-contamination

Randomly packaged gloves promote cross-contamination (present in conventional carton boxes) and do not allow compliance with the WHO guidance, which recommends that ***gloves should be removed from the packaging by touching only the cuff.***[1]

1. World Health Organization. Glove Information Leaflet. 2009.

The flowpack is decontaminated on the inside and decontaminable on the outside

According to the World Health Organization, "any surface with frequent contact with hands requires special attention and more frequent cleaning, ***after thorough cleaning, consider the use of appropriate disinfectants to decontaminate these surfaces".***[1]

A conventional card box is a hand-touch surface and cannot be disinfected*, which contributes to an unclean environment, even in surgical/clean room and, due to its composition, releases particles into the environment.*

Global Guidelines for the preventions of surgical site infections - WHO, 2018

Example of cleaning frequencies in operative and postoperative care areas

Every patient *Every patient, if used* *Enhanced* *If soiled*

The R.ADVANCE flowpack is ***decontaminated on the inside and decontaminable on the outside*** *- its innovative packaging made with recycled plastic allows it to be* ***disinfected whenever necessary.***

1. *World Health Organization. Global Guidelines for the preventions of surgical site infections. 2018.*

R.ADVANCE Dispenser: pioneering the use of gloves at the point of care

Preservation of glove integrity: *The R.DISPENSER is designed to maintain the integrity of gloves, protecting them from damage, dirt, or contamination.*

Individual glove retrieval: *This device allows for the individual retrieval of gloves, reducing waste and ensuring only the necessary quantity is used.*

Compliance with WHO guidelines: *Allows the gloves to be gripped by the cuff and one-by-one as recommended by WHO.*[1]

Hygiene and contamination control: *In addition to glove protection, the R.DISPENSER helps maintain a more hygienic environment, as gloves are shielded from contamination while stored in the dispenser.*

Ease of use: *The operation of the dispenser is simple and intuitive, making it accessible to all users, regardless of their level of experience.*

Strategically placed at the point of care: *Giving HCPs the option of using or not using gloves at the right time, in line with WHO recommendations of glove usage and waste reduction.*

1. *World Health Organization. Glove Information Leaflet. 2009.*

What if...

In addition to all the other benefits, these gloves were sustainable by design?

R.ADVANCE: Sustainable by design

*Just a **15% reduction in the use of examination gloves** across the health and social care sector in England would bring a **£24 millions saving, and a 27,000-tonne carbon reduction.**[1]*

SUSTAINABILITY

ENVIRONMENTAL

Longer usage lifespan

Recycled and recyclable materials

Less defective gloves = less waste

Repurposing defective gloves to produce shoe soles

SOCIAL

Increased safety for HCPs and Patients

Mitigation of cross-contamination risks

Less hospitalizations

Less deaths

ECONOMIC

***Fewer costs with beds occupied** in prolonged hospitalisations due to HCAI's*

*Fewer defective gloves result in **lower waste-related costs***

*The flowpack and dispenser can be placed **closer to the patient, precisely where HCP's have to decide** whether or not they need gloves to perform the procedure*

1. Focusing on today's issues in decontamination. Clinical Services Journal. 2023;22(8):61-64


By reducing the amount
of waste produced,
we and the environment win.
protectingthefuture

No more "What ifs"

Made in Europe, in a controlled environment

- Our gloves are produced in **Portugal, in a fully automated production line**, **within a controlled environment** (HEPA filters), **with no human intervention**, thus assuring a significantly reduced bioburden (the purest nonsterile gloves).

Inspection of 100% of gloves produced

- **RACLAC inspects 100% of its gloves and removes the non-conforming gloves,** while companies manufacturing the alternative standard gloves AQL (1.5) only inspect 500 out of each 4.000.000 batch.

AQL 0.25

- R.ADVANCE has **the lowest AQL in the world**, reducing by **-86% the risk of defects vs. the current standards (AQL 1.5).**

Increased resistance and comfort

R.ADVANCE gloves feature:

- The R.TECHPURE.02 formula, which includes a higher concentration of nitrile, providing **greater resistance during procedures** (10~12 newtons, compared to the standard 6 newtons).
- The R.SLIP formula, offering a **second-skin feeling, with outstanding comfort and preserved sensitivity.**

*Safety in your hands with **R.ADVANCE**, a **unique concept in the world***

Innovative and patented flowpack

- ***Decontaminated on the inside** and **decontaminable on the outside**.*
- ***Air and watertight**, to preserve the gloves' low bioburden until they reach Healthcare Professionals' hands.*
- *A design which allows for the **extraction of one glove at a time by the cuff, following WHO guidelines.***
- *The R.CLOP opening and closing system **ensures the package remains airtight even after it has been opened and closed several times**.*

Pioneering dispenser

- *The R.ADVANCE dispenser was **designed to protect gloves from damage or contamination from the surrounding environment**.*
- *Allows for **individual retrieval of gloves by the cuff**.*
- *It is **strategically placed at the point of care**, giving healthcare professionals the option of using or not using gloves at the right time, in line with WHO recommendations.*

Sustainable by design

- *We inspect 100% of the gloves manufactured, **removing the non-conforming gloves** from production **and introducing them into the circular economy**, as well as deliver **the highest level of safety** to hospitals and clinics.*
- ***The innovative flowpack** allows the extraction of gloves one by one, reducing waste in hospitals, thus contributing to a more sustainable and safer practice.*

About us

RACLAC: Protecting People

RACLAC is a leading European Company *in the development, design, and manufacturing of single-use medical and non-medical devices. It's also the owner of the* ***first production unit for examination gloves in Europe****.*

We are ***revolutionizing protection and safety standards for the healthcare****, pharma and food industries.*

At our core, we hold a deep environmental commitment to Protect the Future. We are driven by the vision of carbon neutrality, making sustainable choices every step of the way.

Elevating protection through innovation

2007
Foundation

2009
Launch of the brand rubbergold

2010
Certification ISO 9001

2011
Certification ISO 13485

2012
Registration on INFARMED
Launch of new portfolio

2015
New facilities

2016
Start of the project for Europe's Ist Glove Factory
Creation and certification of the sterile MD porfolio
Shareholder's entry: Vallis Capital Partners

2017
Launch of the brand nexderma

2018
Kick off of Europe's Ist Glove Factory
Nitro Project
Validation of the production concept for R.Advance in pilot project

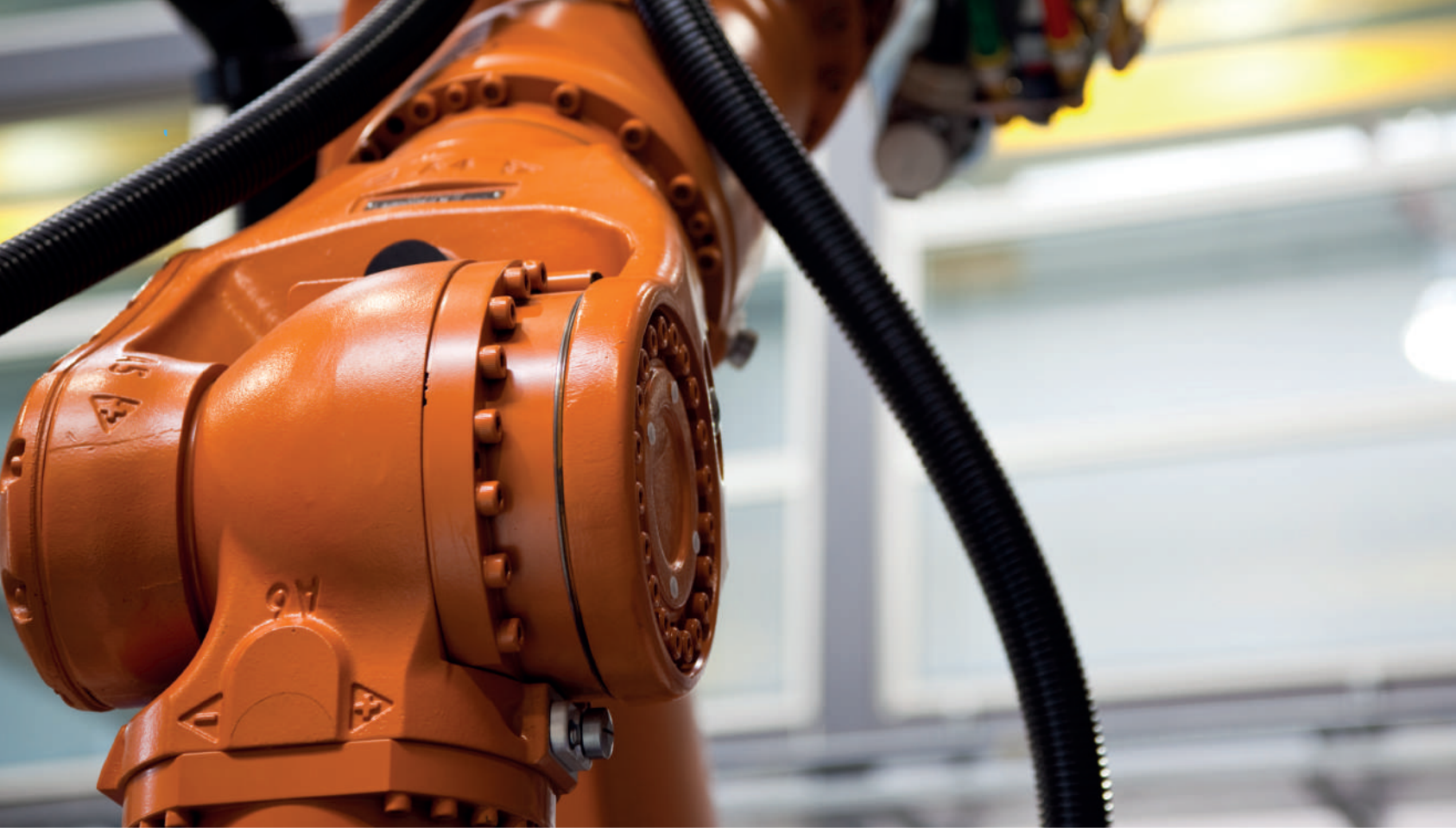
2019
Launch of the brand SELECARE

2020
Ist European examination glove manufactured at RACLAC

2021
Launch of the eco-friendly range rubbergold

2022
Launch of the safest glove R.ADVANCE

2023
Launch of the R.Dispenser



Elevating protection through innovation

- ***Founded in Europe**, in 2007*
- ***First factory for manufacturing gloves** in Europe*
- ***Cutting-edge technology** and a commitment to continuous improvement*
- ***The first fully automated production unit for examination gloves intellectually property of RACLAC, S.A.:***

  Closed facilities | HEPA filters* | Water treatment | 100% automated production line

**HEPA (high-efficiency particulate air) is a type of pleated mechanical air filter. This type of air filter can theoretically remove at least 99.97% of dust, pollen, mould, bacteria, and any airborne particles with a size of 0.3 microns (µm).*

Protecting the environment

At RACLAC, we firmly believe that environmental commitment is not just a choice, but an absolute necessity. Sustainability is deeply ingrained in our investment strategies, guiding our actions towards a greener future.

Some of our key initiatives:

- *Wastewater pre-treatment plant, where at least 60% of the treated water is reused in the production process*
- *Reuse of rainwater*
- *Plantation in our facilities of 1 tree for each employee*
- *Creation of the "RACLAC Forest"*
- *Production of shoe soles from non-compliant gloves - Circular Economy*
- *Installation of electric vehicle charging stations*
- *Use of recycled and recyclable packaging materials*
- *Installation of photovoltaic panels under development*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