

# UniPharma Group

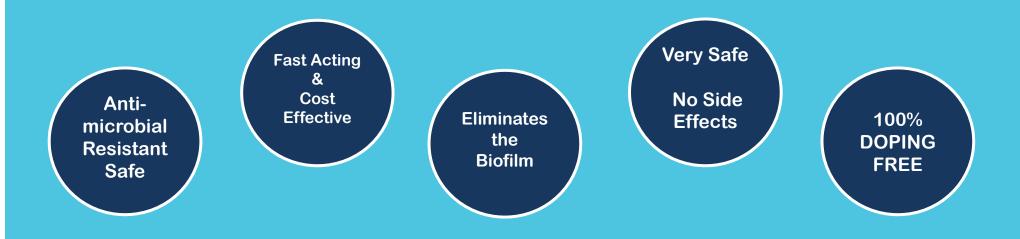
# Distributing Medical Innovations For Wound Care Products

# INTRODUCING



# A new innovative dimension of open wound treatment by Eliminating the Biofilm

Our mission is to help solve the issue of anti-microbial resistance in open wounds, prevent suffering, prevent scarring, treat patients rapidly, effectively and cost effective, and save millions of lives in Africa and globally.



The Problem	4-5
The Solution	6-7
Treatment & Prevention	8
Benefits of PATHELEN <sup>®</sup> Hybrid	9
Solving a National Problem	10
What PATHELEN <sup>®</sup> Hybrid an be used against	11
Pathelen <sup>®</sup> Power	12-13
Ingredients	14
Competitors	15
Effectiveness, Financial Case Study & Application	16-18
Case Studies	19-24
Pathelen <sup>®</sup> Hybrid & Hydrogel Therapy	25
Counterfeit Safety	26
Pathelen Health Care AG (PHC)	27

# CONTENT



THE PROBLEM

# Anti-microbial resistance: a global public health problem

Anti-microbial resistance (AMR) has become one of the biggest threats to global health and endangers other major priorities, such as human development.

Global leaders met at the United Nations General Assembly in New York in September 2016 to commit to fight anti-microbial resistance together. This was only the fourth time in the history of the UN that a health topic was discussed at the General Assembly (HIV, noncommunicable diseases and Ebola were the others).

Reuters issued a study report on 'Surgery death rates in Africa is twice the global average' in January 2018.

It showed about one in five surgery patients developed a complication. Comparisons with international data for elective surgery showed that death rates from elective surgery were 1 percent in Africa compared with 0.5 percent for the global average.

Infections accounted for more than half of complications. The most common procedure was caesarean delivery.



# Antibiotic resistance can affect anyone, of any age, anywhere



Antibiotic resistance is one of the biggest threats to global health, food security and development today.



A growing number of infections – such as wound infection, gonorrhea and salmonellosis – are becoming harder to treat as antibiotics used to treat them become less effective.



Antibiotic resistance occurs naturally, but misuse of antibiotics in humans and animals is accelerating the process.

# THE PROBLEM



Antibiotic resistance leads to longer hospital stays, higher medical costs and increased mortality.



Eliminating the biofilm on a wound is one of the most difficult problems to overcome in wound treatment



## "Forecasted to become the biggest global killer by 2035."

UNITED NATIONS



# THE SOLUTION

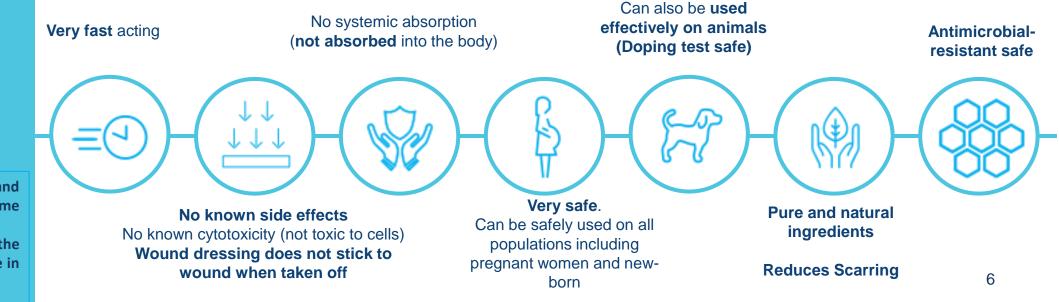
Pathelen Woundpowder and Pathelen Hybrid are the same product.

Pathelen is sold under the Pathelen Wound Powder name in Ghana & Nigeria only. **PATHELEN® Hybrid** is a **European registered Class I Medical Device (CE)**, specifically designed and developed for the prevention and treatment of multi-resistant bacteria (e.g. MRSA) in open wounds. Vitally, bacteria are unable to develop resistance to it, contrary to all antibiotics designed to perform a similar function.

**PATHELEN® Hybrid** eliminates most external bacteria wound infections **within 5-10 days** in most cases, for example when preparing for a wound closure surgery or enhancing growth of granulating tissue on the treated wound.

#### The Product is also registered with:

Nigerian NAFDAC Licensed Class I Medical Device 03-6974 Ghana FDA Licensed Class I Medical Device FDA/D.19-3044 U.S. FDA Regulation Number 878.4018



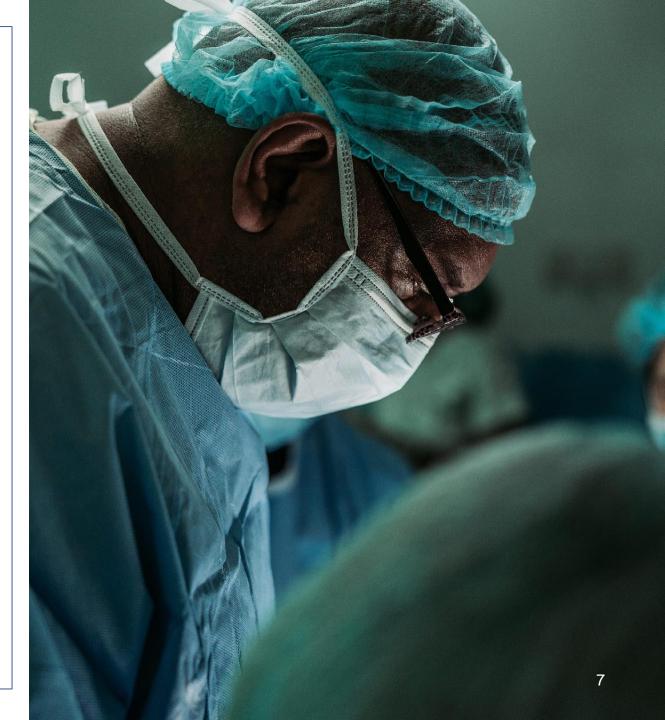
# Common problems with patients with open wounds are

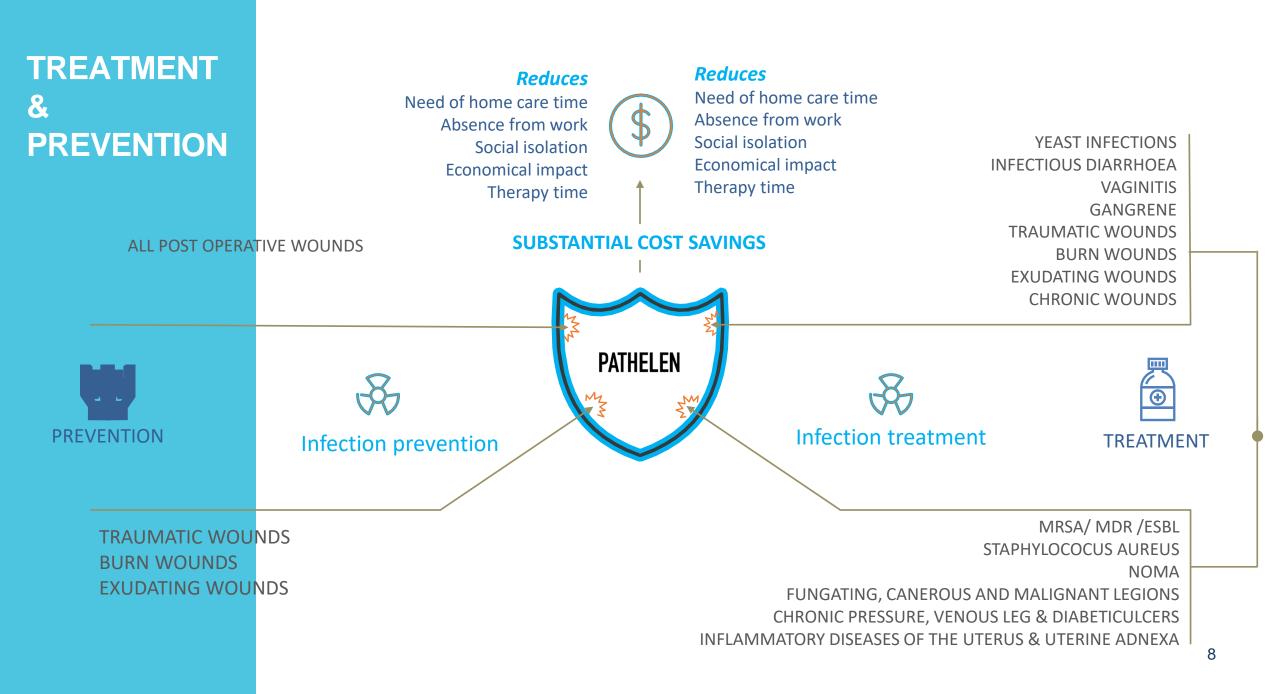
- Rapid destruction of tissue
- Slow detorsion of a wound
- Increase of infectious and inflammatory process (SIRS, sepsis)

# The unique effect of PATHELEN® Hybrid is achieved through various simultaneous complex mechanisms of

- Removal of the biofilm
- Elimination of all germs in the wound
- Sorption of wound exudate
- Preparation of a physiological wound environment with granulating tissue
- Protect the wound against new germs

Eliminates the need for detoxification and systemic antibiotic therapy, even in cases of multi-preparation resistant wound microflora.





# THE **BENEFITS OF PATHELEN®**

For Open Wound Treatment

Based on highly dispersed silicas that have high absorptive, anti-inflammatory properties and supports the healing process.



Helps eliminate the biofilm



Can be used in different fields of practical medicine for the treatment of diseases.

Affinity of proteins in comparison to antibiotics. Antibiotics neither helps topically nor systematically with chronic wounds.

It has a unique healing effect by agglutinating (clump together) microorganisms which have protein molecules on the surface.



Proven by factual and strong evidence, licenses and personal testimonials



Highly accelerated healing time and dressing does not stick to the wound It eliminates most bacterial and fungal wound infections within an average of 5-10 days

# SOLVING A NATIONAL & GLOBAL PROBLEM

# How Pathelen® Can Help

Takes a lot of pressure off any health systems

High reduction of amputations and other long-term issues with infections on chronic wounds

Considerably reduces operations caused by chronic wound infections

Can be used in remote locations preventing high death rates through infections

Substantially reduces death rates caused by infections throughout the region

Reduces the impact to the economy by considerably reducing illness and death rates benefitting social aspects

**Reduces post-op infections** 

Less training and staff cost due to low skill application

# PATHELEN® Hybrid works effectively against



- MRSA/ MDR/ ESBL and multi-resistant gram-negative bacteria
- Infected burn wounds
- Noma
- Diabetic/ neuropathic ulcers
- Exuding wounds
- Stops bleeding almost immediately
- Wounds with resistant nuclei
- Fungating, cancerous or malignant lesions and wounds with necrotic tissue
- Post-operative wounds
- Traumatic wounds
- Elephantiasis open wounds
- Any open wounds with biofilm

PATHELEN<sup>®</sup> Hybrid works most efficiently when a biofilm is present on the wound

**COMING SOON:** Pathelen<sup>®</sup> HydroGel – will work effectively to protect the wound once the biofilm has been eliminated and granulating tissue has formed.

PATHELEN® POWER

# PATHELEN® Hybrid is a more effective and powerful replacement for all other currently available antimicrobial wound treatment devices.

### **PATHELEN®** Hybrid eliminates the shortcomings of other products by creating:

- A universal **hydrophilic-hydrophobic** composition with a highly sorptive and detoxifying effect
  - Hydrophobic molecules and surfaces repel water
  - Hydrophilic molecule or portion of a molecule is one whose interactions with water and other polar substances

#### **PATHELEN®** Hybrid is accessible:

- Pathelen can be administered without the need for specialist training
- It can be used in remote locations where healthcare provision may be sparse
- It can be stored easily

# PATHELEN<sup>®</sup> Hybrid significantly reduces the quantity of infectious complications of pressure ulcers including:

Bacteremia



Sepsis



Abscesses



PATHELEN® POWER

# INGREDIENTS DESCRIPTION

#### Aerosil 300 Pharma

## Aerosil R972 Pharma

#### Is a high purity amorphous anhydrous colloidal silicon dioxide for use in pharmaceutical products (tested according to USP/ NF, Ph Eur. Monograph 0434 and JP).

Applications: Pharmacy, especially solid dosage form and emulsion

#### Properties:

- Used as viscosity increasing agent to thicken and thixotropize liquids
- Improves storage and temperature stability of semi-solid and liquid dosage forms
- Improves distribution of active pharmaceutical ingredients
- Desiccant for moisture-sensitive actives
- Free flow and anti-caking agent to improve powder properties

Is a high purity, amorphous, hydrophobic colloidal silica for use as an excipient in pharmaceutical products (tested according to Ph. Eur. and USP/ NF monographs)

Applications: Pharmacy, especially semi-solid and liquid dosage form

#### Properties:

- Glidant for improving powder flow, especially suitable for very hygroscopic and/or cohesive powders
- Viscosity adjuster for thickening and non-polar pharmaceutical oils
- Stabiliser for water in oil (w/O) emulsion
- May be used to adjust release behaviour of active ingredients

## Benzalkonium Chloride

Also known as BZK, BKC, BAK, BAC, alkyldimethylbenzylammonium chloride and ADBAC, is a type of cationic surfactant. It is an organic salt classified as a quaternary ammonium compound. It has three main categories of use:

- As a biocide
- A cationic surfactant
- A phase transfer agent

Although PATHELEN<sup>®</sup> Hybrid is a powder, it has completely different properties compared to all currently available wound powders on the market. When PATHELEN<sup>®</sup> Hybrid comes into contact with the wound exudate, it transforms into a gel-like substance.

An ordinary wound gel only creates a moist wound environment but does not eliminate enough bacteria and biofilms to ensure a fast-healing process or wound healing at all.

PATHELEN® Hybrid creates a germ-free wound with granulating tissue independent of the state or the immune system.

	PATHELEN <sup>®</sup> Hybrid	OTHER PRODUCTS
Sorption of protein, mgg-1	up to 800	No sorption possible
Sorption of microorganisms,	up to 10.0	No sorption possible
billion g-1		
Osmotic activity in %	377	0.00
Moist wound environment	yes	yes
Wound protection	yes	yes
Adsorption of wound exudate	yes	yes
Removal of biofilm	yes	no

MARKET

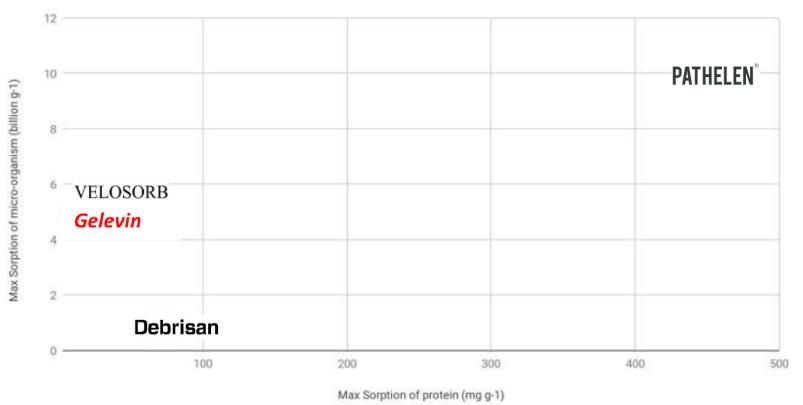
**COMPETITORS** 

Comparison of PATHELEN® Hybrid properties and typical wound gels/ powders on the market"

# PATHELEN® Hybrid is 6.4 x more effective than its closest competitor

Sorption of protein and micro-organisms

Product maximum capability



1) -450mg g-1 sorption of protein

2) **-10 billion** g-1 sorption of microorganisms

# Patient with third degree burns (25% of body)

#### The treatment:

- Debridement of wound surface by surgery
- Intravenous (IV) electrolyte fluid
- Paid medication
- Ongoing medical labour
- Daily bed cost
- Skin grafting (after 5 days of treatment
- Aftercare

**FINANCIAL** 

2019

CASE STUDY

#### **Reasons for cost saving:**

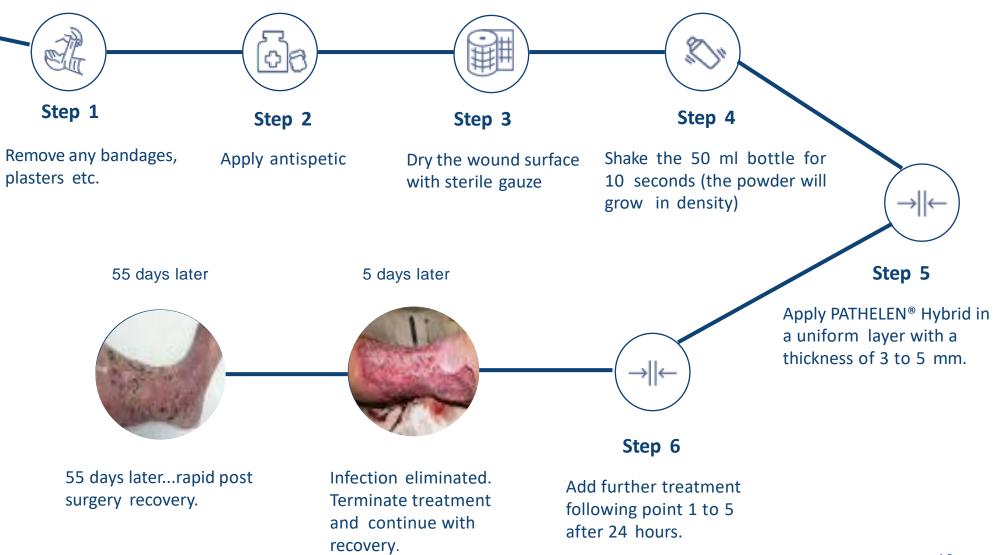
- Fewer applications per patient required
- High effectiveness means patients heal more quickly
- Fewer complications mean patient turnover is higher





MRSA infected ulcer on 65-year-old male.

# APPLICATION PROCESS



#### Patient: Oleg L., 73 y.o.

#### Disease history:

Diabetes mellitus – sickness duration 12 years. Carbuncle of interscapular region – sickness duration 8 days.

#### Local treatment:

- Debridement of wound surface by surgical removal
- Debridement of wound surface by Pathelen®
- 5 days after surgery- granulated tissues.
- After 10 days full recovery.



# CASE STUDY

Examples

#### Patient: Anonymous, 55 y.o.

#### Injury:

Diagnosis : Avulsion injury of the right side of face. Injury resulted in the loss of tissue on the right side of face. There was complete loss of cheek tissue as the cheek wound communicated with the oral mucosa.

Wounds were required to granulate and or were required to heal by secondary intention with epithelialization.

#### Local treatment:

Selected wounds were thoroughly cleaned with Savlon and copiously irrigated with saline. Pathelen was applied to the wound. Vaseline gauze was applied to hold the Pathelen in place, dry gauze was applied, and wound was bandaged lightly with gauze bandage. Dressing was changed every 48 hours.

By day 10 of Pathelen dressings the wound had filled up with granulation tissue with remarkable wound contraction. As a result, will not require the use of a flap to cover the wound she will require a simple split thickness skin graft to cover the wound.





# CASE STUDY

# **Examples**

#### Patient: Jacob A., 28 y.o.

#### Injury:

Diagnosis : open right leg injury, debridement and external fixation done on same-day admission. Extensive laceration over the dorsum of the foot with foul odour, exudate and heavy slough over the surface of the wound

The wound was initially cleansed with normal saline and covered with iodine solution. Unfortunately, wound healing process was slow.



# HUMAN CASE STUDY

## **Examples**

#### Local treatment:

The wound was cleansed with normal saline and Pathelen WoundPowder was applied onto the wound.

Dressing changes were done daily, and the wound showed drastic improvement within few days. There was no foul odour and no discharge



#### Patient: Oleksii T., 41 y.o.

#### Disease history:

**CASE STUDY** 

**Examples** 

Acute rotten pelviorectal abscess. Diabetes mellitus for 2 years.

Hospitalized after 7 days the disease has begun. Leucocytes – 15,5 × 109/l. Sugar in blood – 8,0 mmol/l

#### Local treatment:

Necrectomy by Pathelen® Debridement of wound surface by surgical removal and Pathelen®, autodermoplastics.





#### Patient: Z.V., male, 68 y.o.

#### **Diagnosis:**

Type 2 diabetes mellitus, diabetic foot syndrome neuroischemic form; wound infection of the left foot after amputation of fingers Case relevant history: Ischemic heart disease Hypertensive heart disease; Heart failure Atrial fibrillation is a permanent form

#### Microflora:

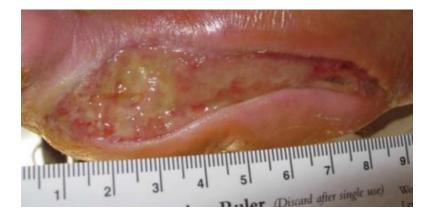
Staphylococcus aureus Staphylococcus epidermidis Enterococcus faecium

#### **Blood tests:**

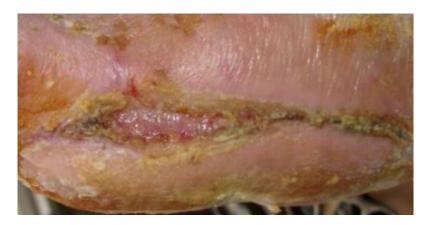
White blood cells (WBCs):  $8,0\times109$  /l Banded neutrophils – 8%. On the lateral surface of the left foot was observed infected wound sized 9 x 3 cm



Wound was covered with 3-5 mm layer of Pathelen Hybrid and covered with antiseptic bandage



Infected Wound



After 26 days 70% of the wound is healed, is clean  $^{\ \ 23}$  and actively epithelialised

# HUMAN CASE STUDY

**Examples** 

#### Patient: Vasiliy S., 69 y.o.

#### Disease history:

Hypopharynx cancer metastasis and neck lymph nodes on the right.

1 year ago - laryngectomy with resection of the hypopharynx. After surgery – course of radiation therapy.

On 4th day after the surgery.

 Massive post-surgery lymphorrhea - MRSA-infected wound

 Necrosis of skin patches: defect of skin 8x10 cm -Denudation of carotid artery in the wound

#### Treatment:

Debridement of wound surface by surgical removal and Pathelen®, autodermoplastics.

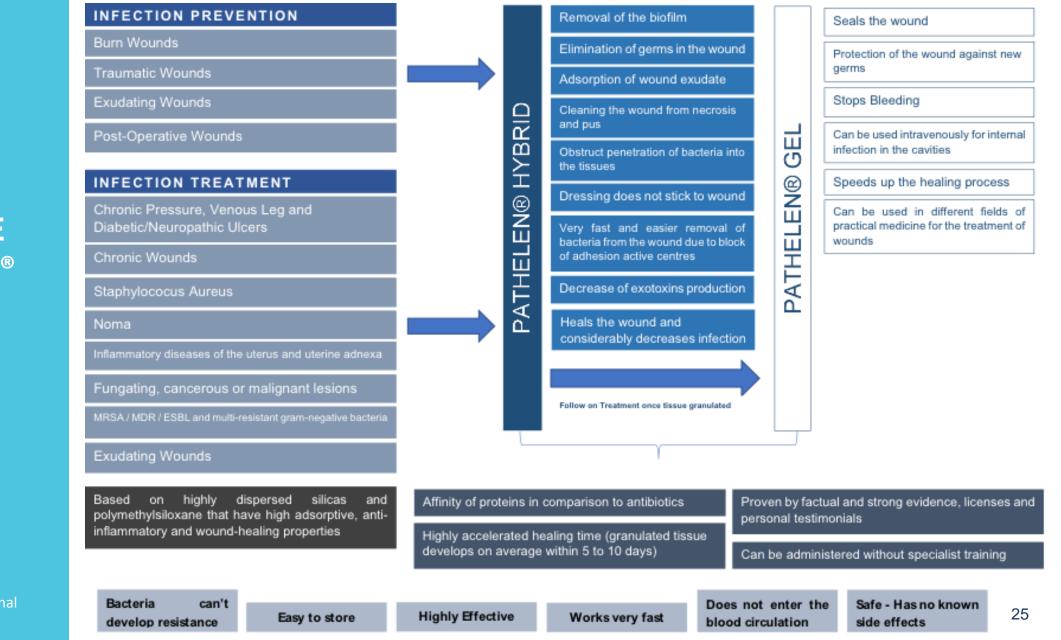




# CASE STUDY

# Examples

# The future of effective wound treatment



# COMPLETE PATHELEN® THERAPY

# Hybrid & Hydrogel

\*(Pathelen<sup>®</sup> Hydrogel in final registration stage)

COUNTERFEIT SAFE PATHELEN<sup>®</sup> Hybrid contains a unique patented formula, which when shaken for 15-20 seconds will grow visibly in density by more than 20 times, creating the advanced sorption property and filling the bottle content.

This change is clearly visible inside the bottle.



## **THIS REACTION CANNOT BE COPIED!**

PATHELEN<sup>®</sup> Hybrid is a development of Pathelen Health Care AG Switzerland.

Led by Chief Scientist and CEO, Andreas Tausch, the company has developed PATHELEN<sup>®</sup> Hybrid over several years. The development was made in close cooperation with various universities and hospitals. PATHELEN<sup>®</sup> Hybrid is protected by several patents and further products of the product family are under development.



# Could you imagine a world without PATHELEN® Hybrid?



DISTRIBUTING MEDICAL INNOVATIONS FOR WOUND CARE PRODUCTS

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