



Hibiwash®
bonded to skin



HIBIWASH® CHLORHEXIDINE GLUCONATE

Hibiwash® is an antimicrobial full-body wash that **bonds to and cares for skin, whilst killing microorganisms.**

It is your **trusted partner** in helping prevent infections, promote skin's integrity and save time before performing surgical procedures.

With 4% Chlorhexidine Gluconate

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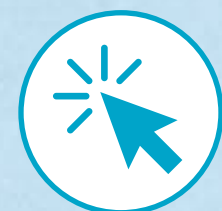
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SURGICAL SITE INFECTIONS

AN ONGOING PROBLEM

Managing surgical site infections (SSIs) and hospital acquired infections (HAIs) is a real and growing problem, with serious implications.

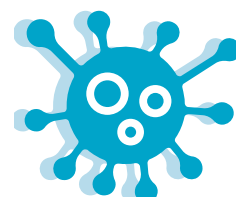
An SSI is an infection that occurs after an invasive operation in the location where the surgery took place. It is the second most common type of HAI in the EU.¹ Studies have shown that the patient's skin is responsible for most of the pathogens that cause SSIs.² Up to 33 % of the population naturally carry Staphylococcus aureus on their skin. Staphylococcus aureus can also be found on the surgeons' hands.³



11.8% avg. of surgeries in low and middle income countries will result in a SSI⁴



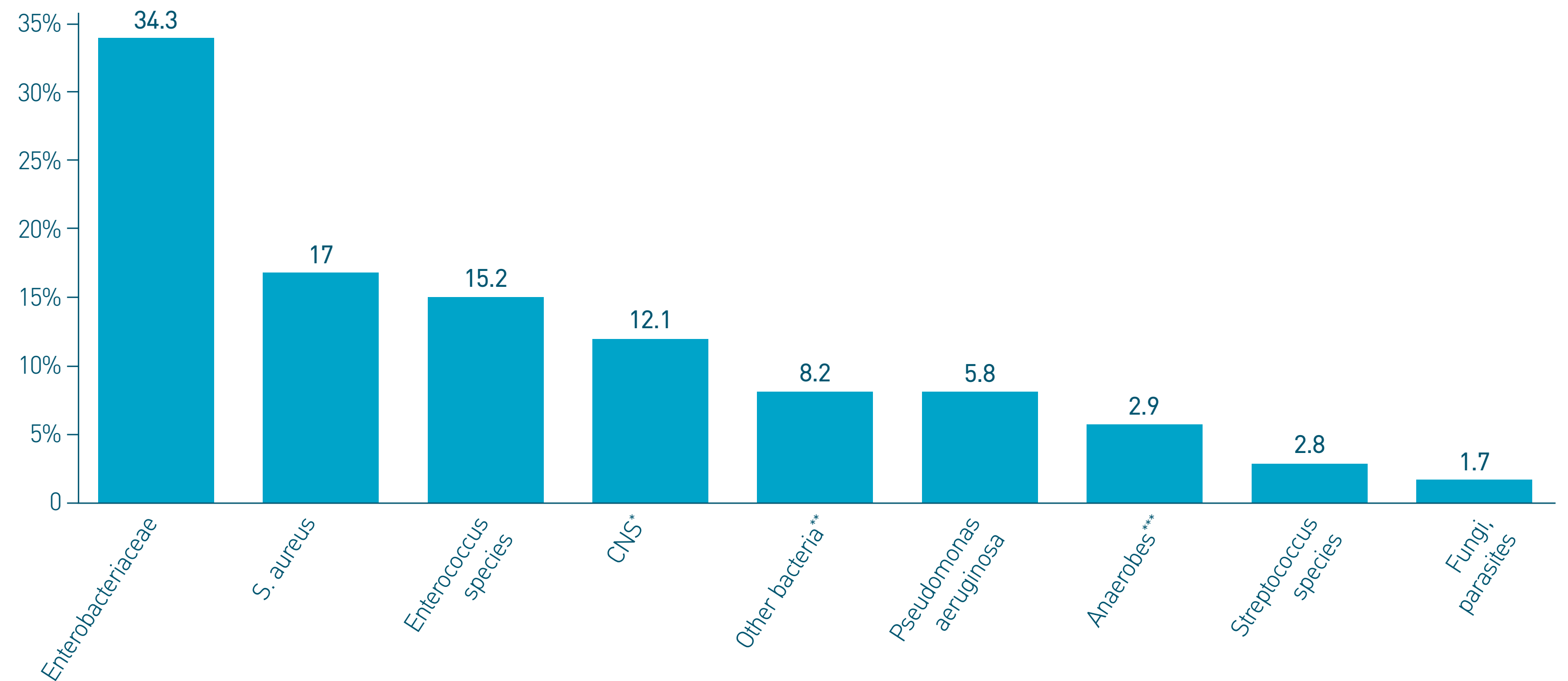
7% of patients in high income countries will have HAI⁵



10% of lower income countries will have a HAI⁵

PROPORTION OF SSI WITH ORGANISM DATA (%)

Inpatient and readmission cases (n=9,858)⁶



* Hibiwash® is not proven to be effective against S. haemolyticus. ** Mostly comprising unspecified diphtheroids, 'other' gram-positive organisms and bacilli. Hibiwash® is not proven to be effective against Stenotrophomonas maltophilia. *** Hibiwash® is not proven to be effective against Cdiff spores.

SURGICAL SITE INFECTIONS...

...RESULT IN AN
ESTIMATED

**19.1 BILLION
EUROS⁴**

IN ADDITIONAL COSTS

...INCREASE THE
LENGTH OF STAY BY

**6.5 DAYS
IN THE EU⁴**

...HAVE A

**NEGATIVE
IMPACT**

ON PATIENT QUALITY OF
LIFE AND ON GLOBAL
HEALTHCARE SYSTEMS

...TRIGGER FURTHER
DEPENDENCE OF

ANTIBIOTICS,

POTENTIALLY LEADING
TO AN INCREASE IN
ANTIBIOTIC RESISTANCE



A RISK TO ELIMINATE

With the increased focus on infection prevention globally, now is more important than ever to minimise the risks of healthcare associated infections, such as SSIs.

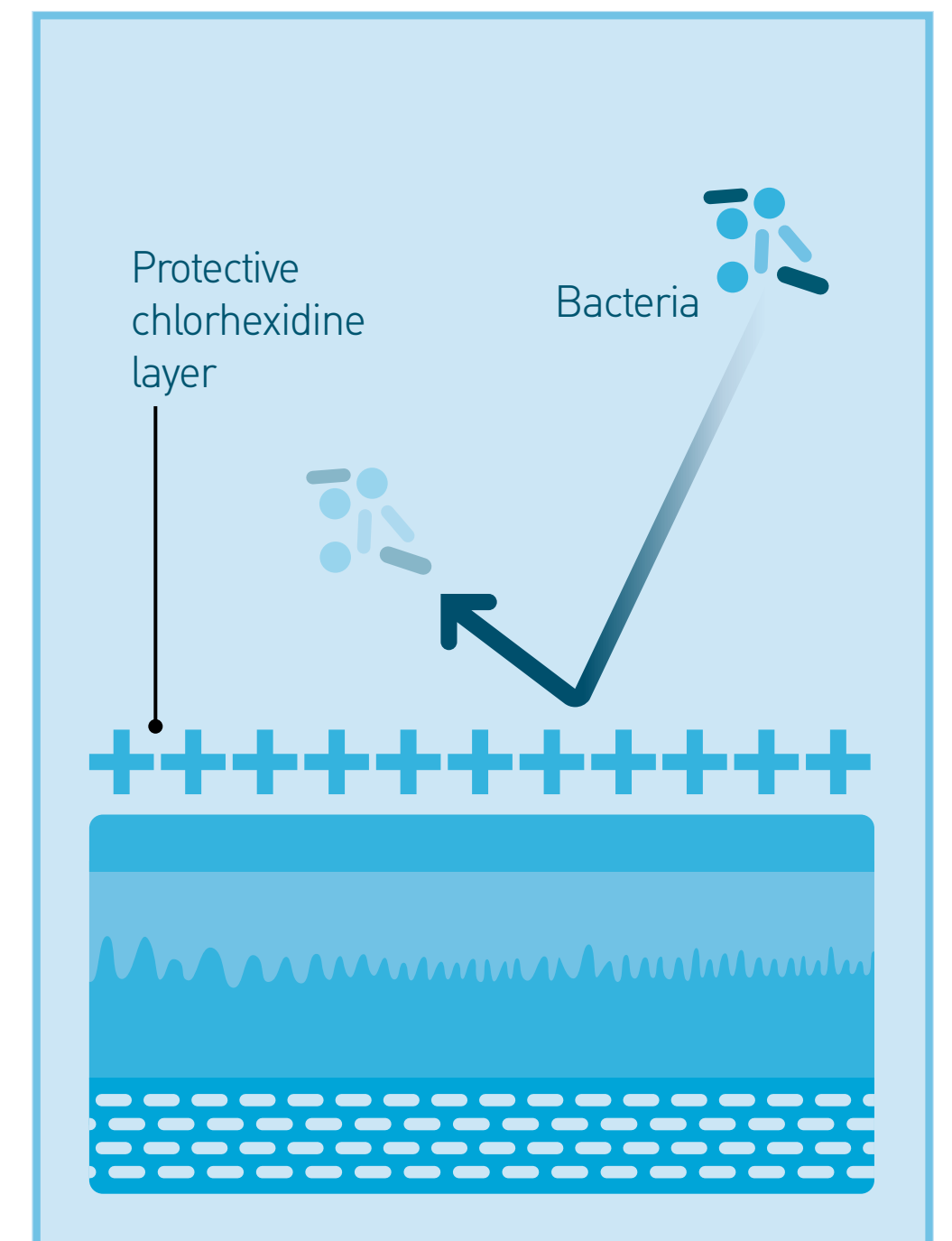
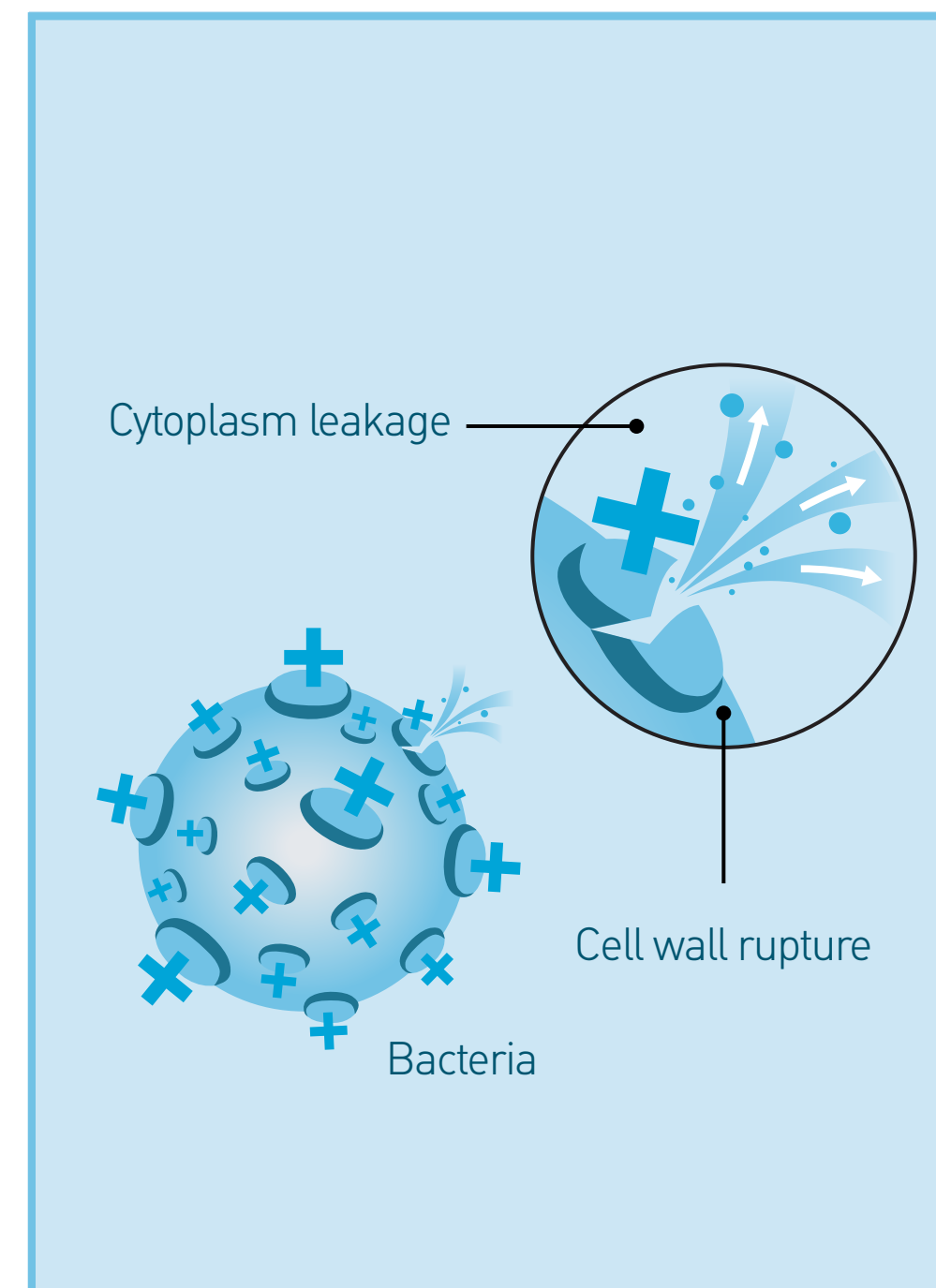
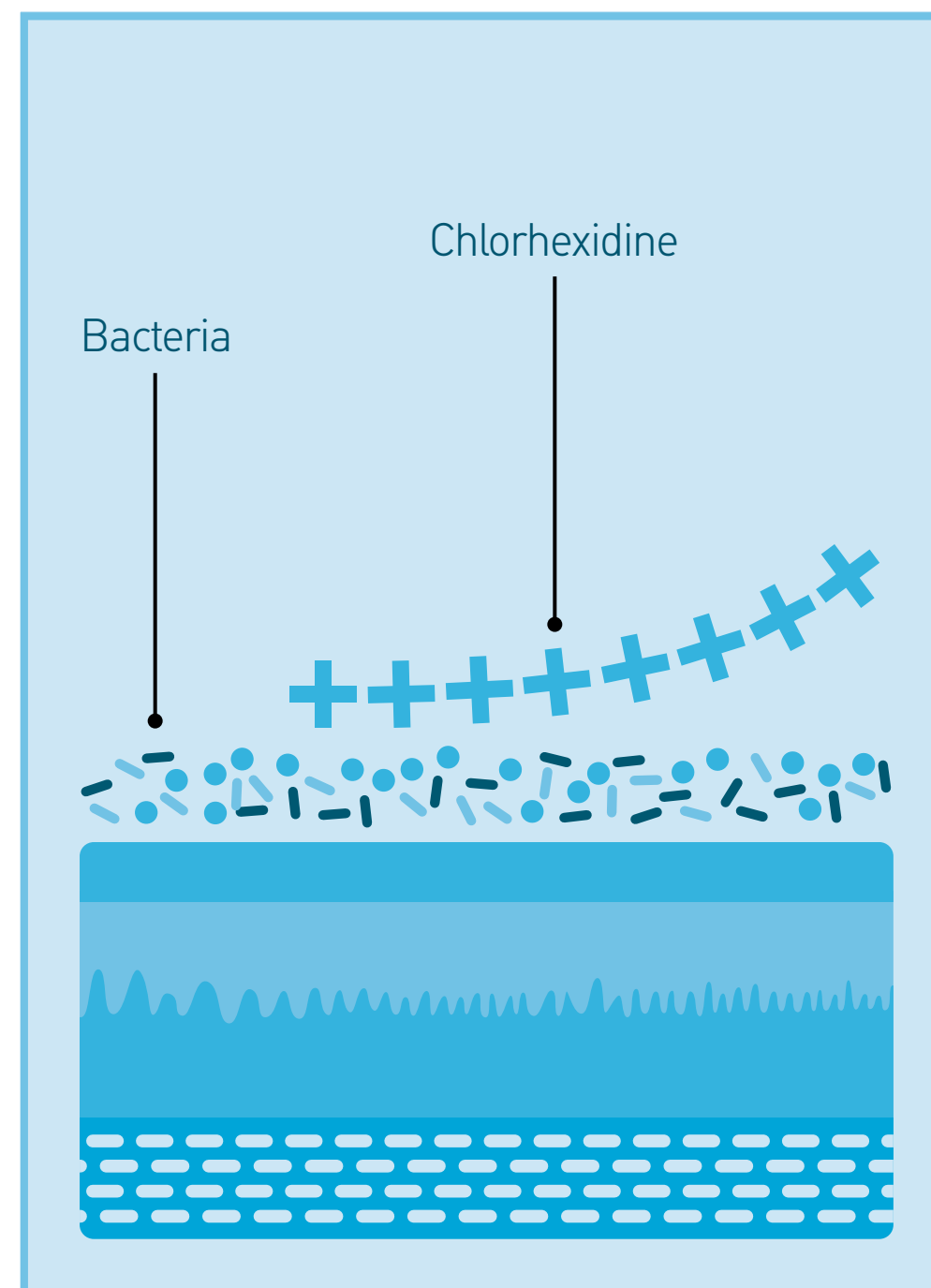
Did you know:

...that Hibiwash® can be used for effective prevention against the most common causes of SSIs?



CHLORHEXIDINE GLUCONATE – HOW DOES IT WORK?

CHG binds to the cell wall of the bacteria causing it to rupture, leading to cell death. CHG molecules bind to the proteins in human tissues and provide a layer of prolonged protection.⁷



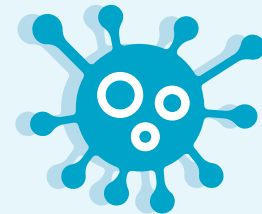
HIBIWASH®

AN EFFECTIVE ANTIMICROBIAL SKIN CLEANSER PROTECTING THE PATIENT IN THE HOSPITAL AND AT HOME



Ideal for whole body washing for preadmission patients

- Post-operative infections reduced to 8% from 17.5% in a study of 341 patients using Chlorhexidine whole body washing.⁸
- 20-fold reduction in skin bacteria count after showering three times with 4% Chlorhexidine in a randomised controlled trial.⁹
- Hibiwash® reduces skin flora by 94% with the first whole body wash and then by a further 77% with the second.¹⁰



Effective in a wide range of microorganisms

Hibiwash® is effective against a wide range of microbes including Gram positive and Gram negative bacteria, yeast, fungi and viruses, and reduces bacterial load more efficiently than povidone iodine.^{11,12} In combination with a nasal antibiotic Hibiwash® was shown to significantly decrease the risk for hospital associated *S. aureus* infections by up to 60%.¹³



Fast acting with a long lasting effect

Hibiwash® is not absorbed into the skin but binds to it, forming a protective layer even after the rinse off that efficiently kills microorganisms, for hours after application.¹⁴ Furthermore, unlike povidone iodine, Hibiwash® is not inactivated by bodily fluids.¹⁶



Tough against microbes and gentle to the skin^{17,18}

Hibiwash® is dermatologically tested, it has no colour, no fragrance, no traces of soya oil and contains emollients. It has been shown to be gentle on the skin even when used frequently. This is beneficial since repeated application of Hibiwash® has been shown to increase the antimicrobial efficacy.¹⁹

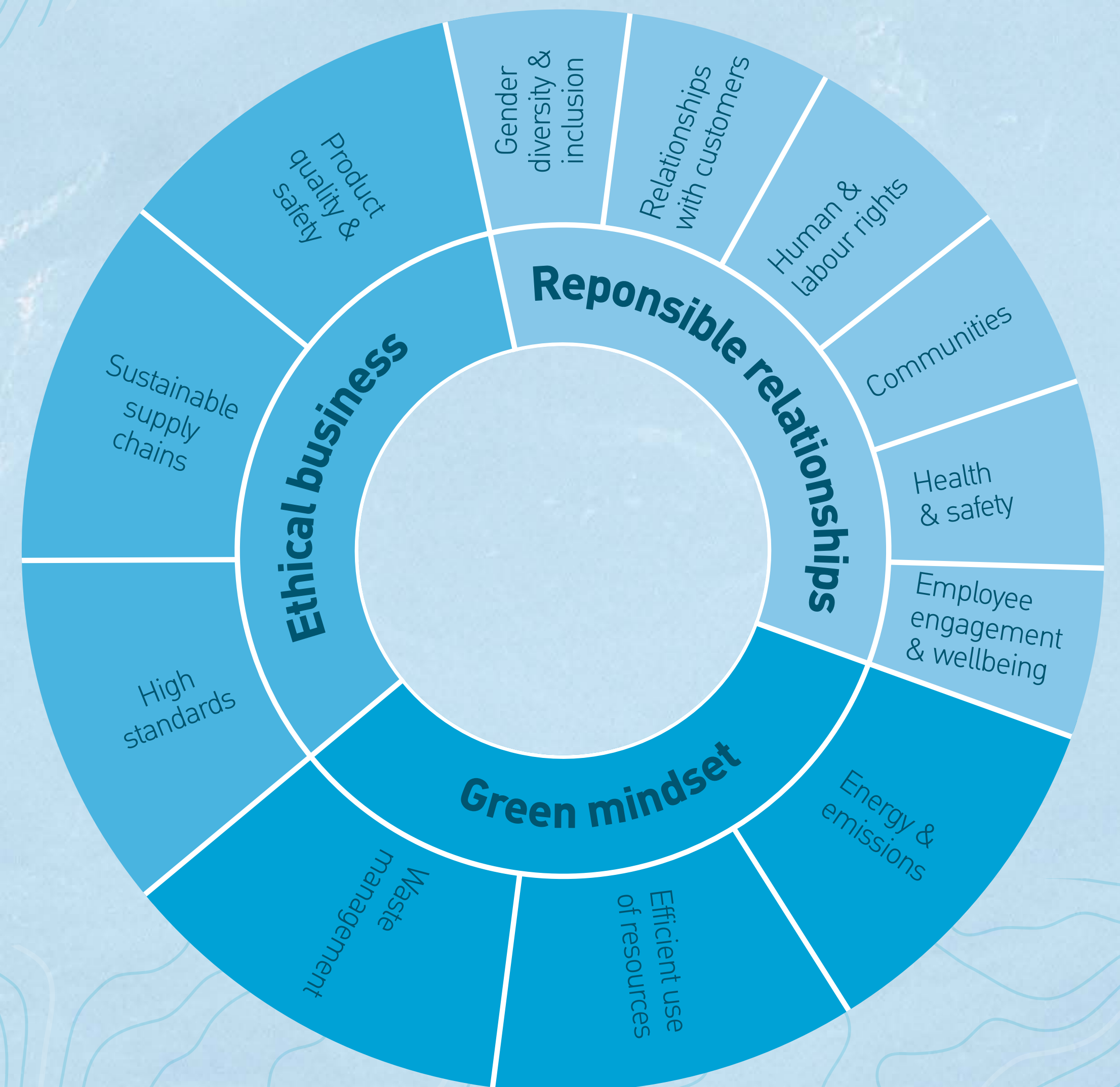
Efficacy information

*PhEur 5.1.11
– bactericidal and
yeastcidal*

Please speak to your Mölnlycke contact person for information on product codes, on packaging and product accessories in your local market.

At Mölnlycke, we are committed to becoming a more sustainable business.

Hibiwash® is part of our sustainability development. Our primary packaging (bottles) and transport shippers (cardboard) are all made of recyclable material.



PROTECTING YOUR PATIENTS

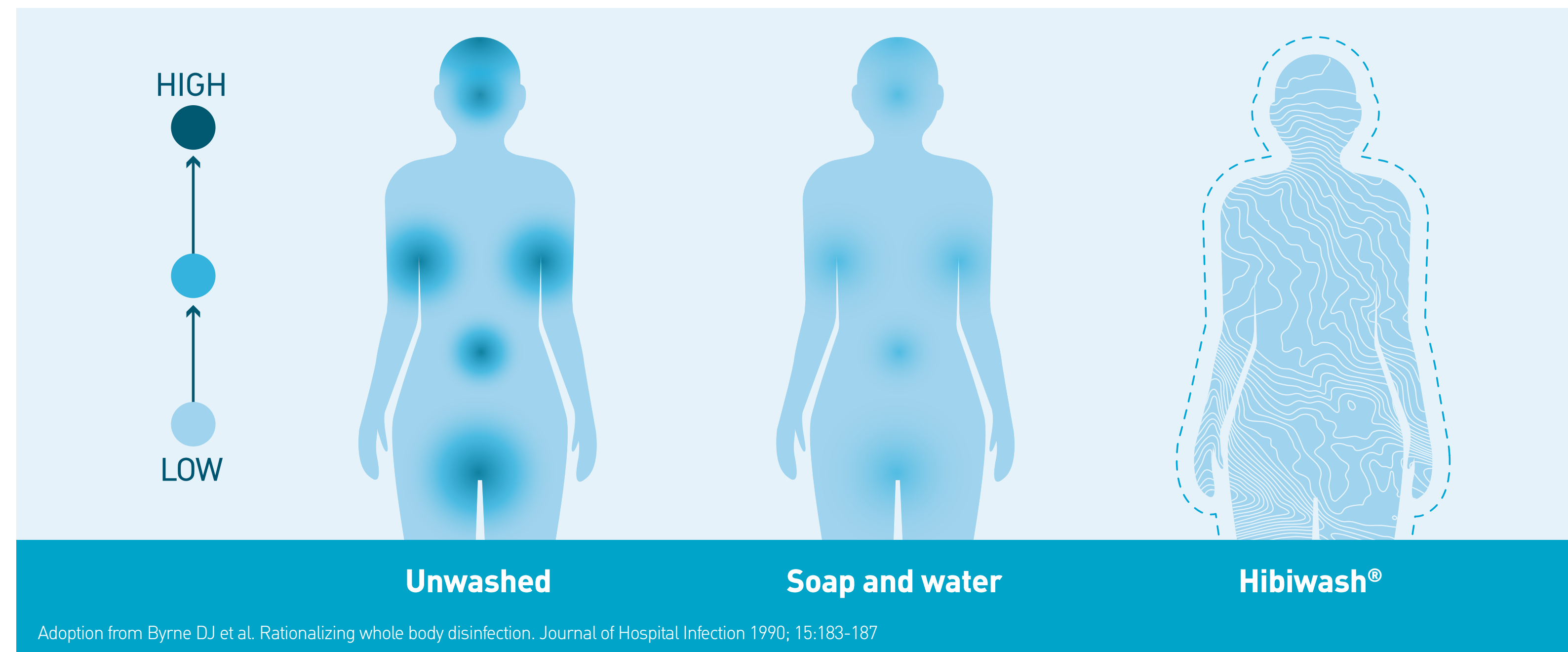
Hibi products have been used in hospitals for many decades



SKIN – THE SOURCE OF THE PROBLEM?

Studies have shown that the patient's skin is responsible for most of the pathogens that cause SSIs.⁵ Up to 33% of the population naturally carry Staphylococcus aureus on their skin.^{2,3}

MICROORGANISMS RESIDUE LEVELS AFTER WASHING



What if there was an easy way to ensure a clean surgery?

There is! It's Hibiwash®

With easy to follow instruction Hibiwash® can be used for pre-operative and post-operative whole body washing to reduce the chance of SSIs.

Kills a **vast number** of microorganisms¹¹

Provides **hours of** protection¹⁵

Gentle to skin¹⁸

Help us to reduce the **11 in 100 chance** of a surgical site infection.²⁰

Together let's move towards zero.

Find out more at www.molnlycke.co.uk



Hibiwash® Chlorhexidine Gluconate

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Hibiwash®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 4% w/v

(incorporated as Chlorhexidine Gluconate Solution)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Hibiwash® is an antimicrobial preparation for pre-operative surgical hand disinfection, antiseptic hand washing on the ward and pre-operative and post-operative skin antisepsis for patients undergoing elective surgery.

4.2 Posology and method of administration

For external use only.

Pre-operative surgical hand disinfection

Wet the hands and forearms, apply 5 ml of Hibiwash® and wash for one minute cleaning the fingernails with a brush or scraper. Rinse, apply a further 5 ml of HibiWash and continue washing for a further 2 minutes. Rinse thoroughly and dry.

Antiseptic handwash on the ward

Wet the hands and forearms, apply 5 ml of Hibiwash® and wash for 1 minute. Rinse thoroughly and dry.

Pre-operative skin antisepsis for the patient

The patient washes his whole body in the bath or shower on at least 2 occasions, usually the day before and the day of operation as follows: The day before operation the patient washes with 25 ml of Hibiwash® beginning with the face and working downwards paying particular attention to areas around the nose, axillae, umbilicus, groin and perineum. The body is then rinsed and the wash repeated with a further 25 ml, this time including the hair. Finally the patient rinses his entire body thoroughly and dries on a clean towel. This procedure should be repeated the following day. Patients confined to bed can be washed with Hibiwash® using a standard bed-bath technique. Conventional disinfection of the operation site will then be performed when the patient is in theatre.

Post-operative skin antisepsis for the patient

The patient washes his whole body, excluding the operation wound, in the bath or shower usually on the third day after operation using the procedure described above.

Children and elderly patients

There are no special dosage recommendations for either elderly patients or children. The normal adult dose is appropriate unless recommended by the physician.

4.3 Contraindications

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use

Hibiwash® contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Hibiwash® should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Hibiwash®, care must be taken to ensure no excess product is present prior to application of the dressing.

Hibiwash® is flammable. Do not use with electrocautery procedures or other ignition sources until dry.

Isopropyl alcohol may very rarely cause skin irritations such as erythema, dryness, contact allergies, burning sensation.

For external use only. Avoid contact with the brain, meninges and middle ear. In patients with head or spinal injuries or perforated ear drum, the benefit of use in pre-operative preparation should be evaluated against the risk of contact. Hibiwash® must not come into contact with the eye. Serious cases of persistent corneal injury, potentially requiring corneal transplant, were reported following accidental ocular exposure to chlorhexidine containing medicinal products despite taking eye protective measures due to migration of solution beyond the intended surgical preparation area. Extreme care must be taken during application to ensure that does not migrate beyond its intended application site into the eyes. Particular care should be taken in anaesthetised patients, who are unable to immediately report ocular exposure. If Hibiwash® comes into contact with the eyes, wash out promptly and thoroughly with water. An ophthalmologist's advice should be sought.

Do not inject or use in body cavities.

4.5 Interaction with other medicinal products and other forms of interaction

See Section 6.2.

4.6 Fertility, pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of Hibiwash® as a handwash during pregnancy and lactation. Therefore no special precautions are recommended.

4.7 Effects on the ability to drive and use machines

None have been reported or are known.

4.8 Undesirable effects

Very Common ($\geq 1/10$); Common ($\geq 1/100, < 1/10$); Uncommon ($\geq 1/1,000, < 1/100$); Rare ($\geq 1/10,000, < 1/1,000$); Very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:

Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune system disorders:

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Eye disorder:

Frequency not known: Corneal erosion, epithelium defect/

corneal injury, significant permanent visual impairment*. Injury, poisoning and procedural complications: Frequency not known: Chemical burns in neonates.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

This has not been reported.

Accidental ingestion: chlorhexidine taken orally is poorly absorbed. Treat with gastric lavage using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants, ATC code: D08AC02

Mode of action – chlorhexidine has a wide range of antimicrobial activity. Chlorhexidine is effective against a wide range of gram-negative and gram-positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures. Because of its cationic nature, chlorhexidine binds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

5.2 Pharmacokinetic properties

Retention and uptake kinetics and factors influencing the pharmacokinetics. Chlorhexidine appears to be very poorly absorbed. No blood levels were detected during a 3-week simulated clinical use of Hibiwash®.

5.3 Preclinical Safety data

Chlorhexidine is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poloxamer 237

Isopropyl alcohol

Cocamidopropylamine oxide

Glycerol

Macrogol-7 Glycerol Cocoate

Gluconolactone

Purified water

Sodium hydroxide (for pH-adjustment)

6.2 Incompatibilities

Chlorhexidine is incompatible with soap and other anionic agents.

Hypochlorite bleaches may cause brown stains to develop in fabrics, which have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf Life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottles containing 125 ml, 250 ml, 500 ml and 5 litres.

6.6 Special precautions for disposal and other handling

See section 4.4.

7. MARKETING AUTHORISATION HOLDER

Regent Medical Ltd

Medlock Street

Oldham

Lancashire

OL1 3HS

United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 22099/0003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/10/2023

10. DATE OF REVISION OF THE TEXT

07/2024

*Cases of severe corneal erosion and permanent significant visual impairment due to inadvertent ocular exposure have been reported post-marketing, leading to some patients requiring corneal transplant (see section 4.4).



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MARKETING AUTHORISATION NUMBER(S) HQIM005143UK

