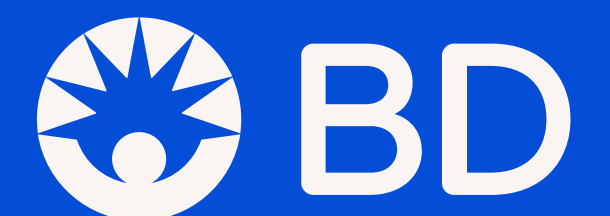


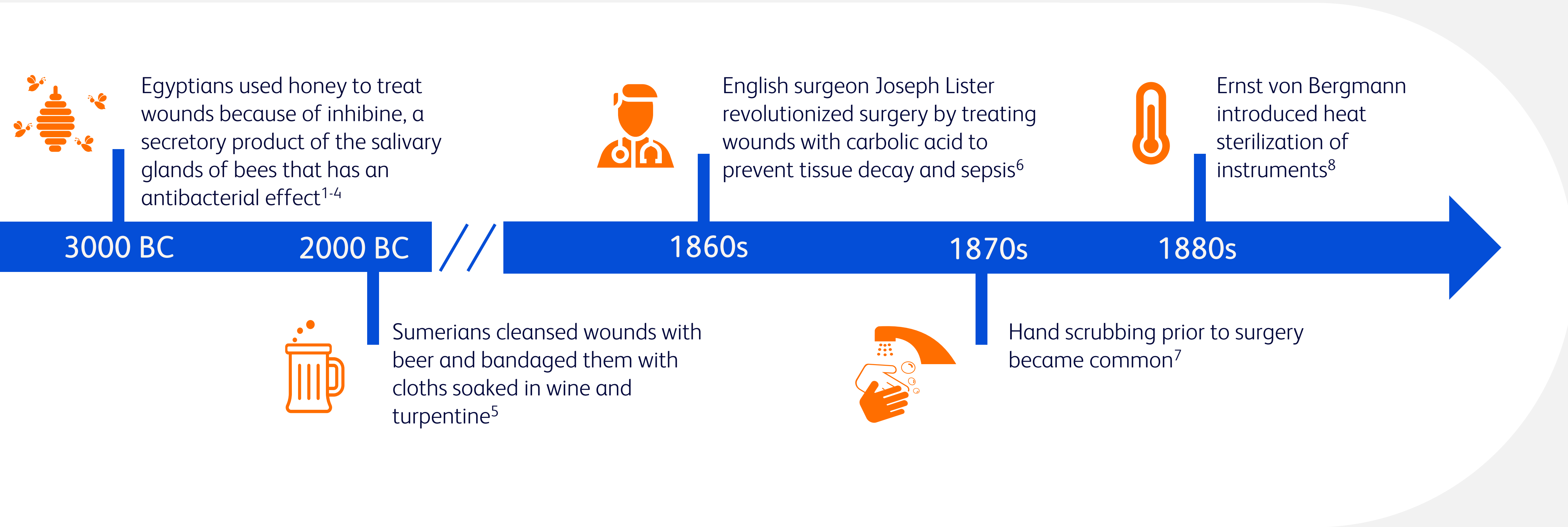


Elevating the standard

BD ChloraPrep™ and BD PurPrep™ patient preoperative skin preparations
with sterile solution



Antisepsis has evolved



Important advances continue to be made

Older standards

Latest advancements

Antiseptic formulations

Single agents

Lack either immediate or persistent activity¹

Dual formulations

More effective at killing bacteria^{2,3}

Delivery methods

Bulk solutions

High risk of contamination and manipulation⁴; application method may result in hand-to-site contact

Single-use applicators

Eliminate cross-contamination; does not allow for solution manipulation; no-touch application

Solution sterility

Nonsterile solutions

Risk of intrinsic contamination during manufacturing⁵

Sterile solutions

Minimizes risk of intrinsic microbial contamination⁵

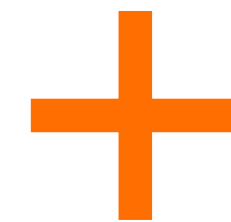
Recent evolution of patient preoperative skin preparation

BD: At the forefront of the antiseptic evolution

BD ChloroPrep™ patient preoperative skin preparation with sterile solution elevates the standard by assuring product sterility

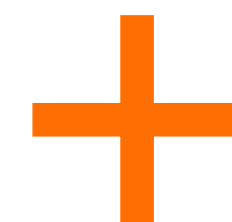
Dual formulation

2% chlorhexidine gluconate (CHG) + 70% isopropyl alcohol (IPA), meeting leading guidelines for patient preoperative skin preparation^{1-3*}



Single-use applicator

Packaged in a proprietary one-step, single-use, sterile applicator

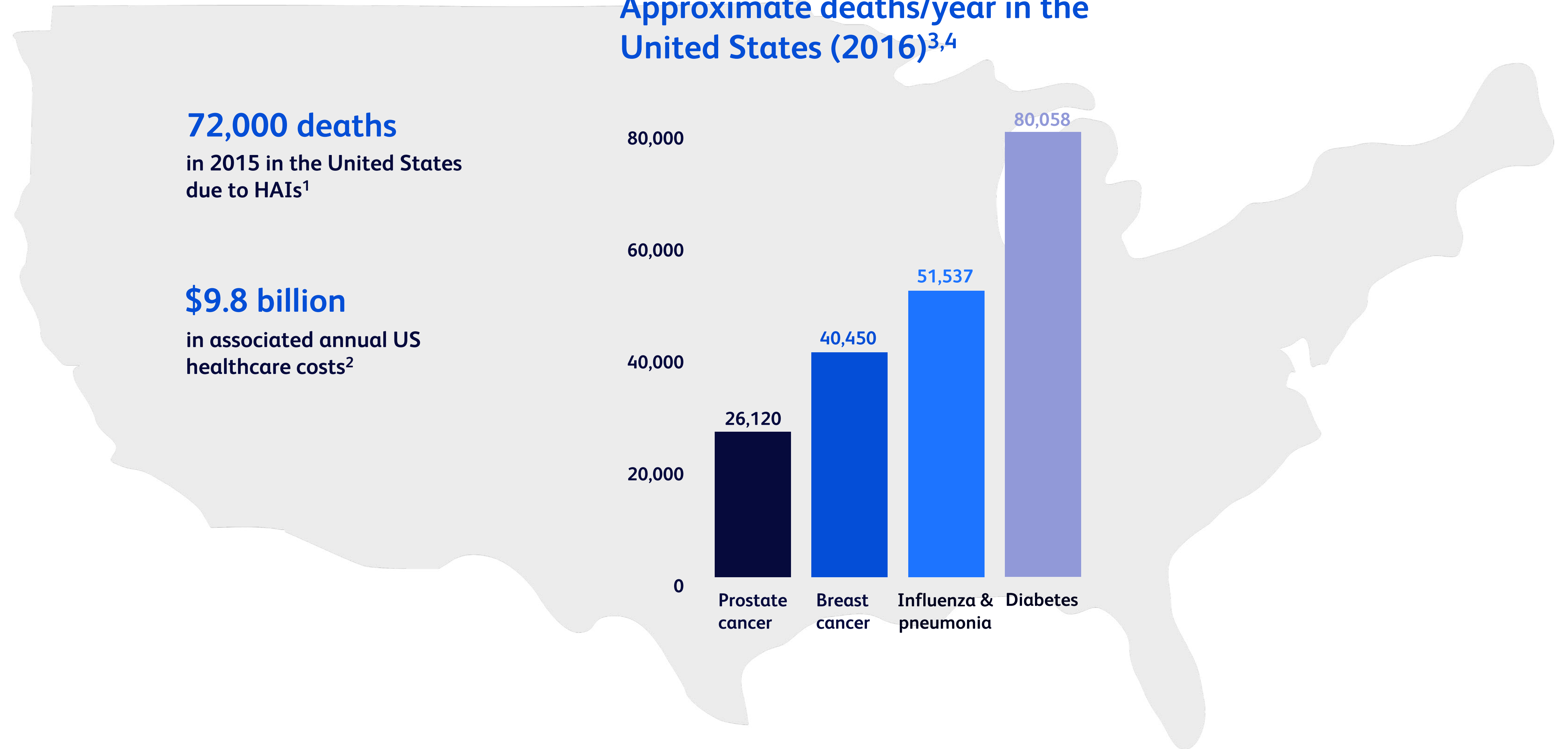


Sterile solution

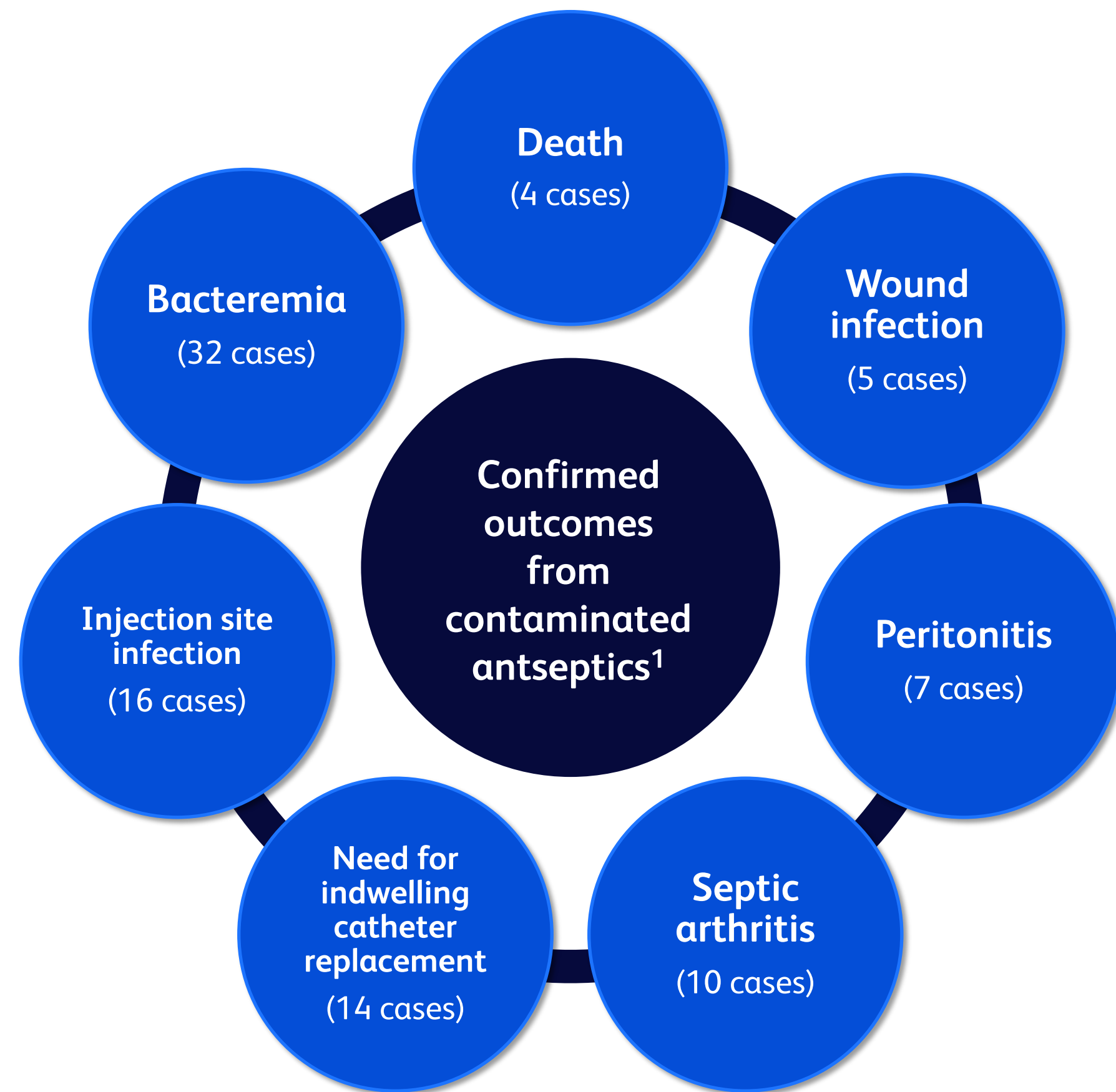
New, advanced technology delivers the only commercially available CHG-based, sterile solution skin preparation in the United States

Why sterilize?

Healthcare associated infections (HAIs) are a major threat



Contaminated antiseptics are a documented cause of HAIs



Outcomes may be underreported for a range of reasons, including²

- Disposal of contaminated product before infection is discovered
- Inconsistent contamination within the same lot

2 mechanisms are responsible

Extrinsic contamination:

end-user based; can result from¹:



Insufficient aseptic technique used during product handling



Contaminated water used to dilute the antiseptic



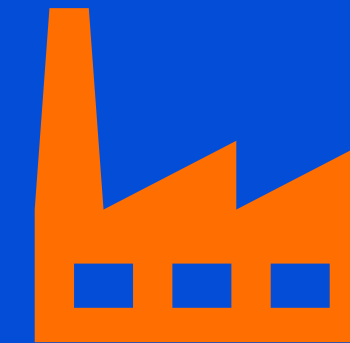
Product stored under nonsterile conditions

Intrinsic contamination:

production-based; has been linked to¹:



Contaminated pharmaceutical water supply



Nonsterile manufacturing environment

Intrinsic contamination has prompted product recalls

2000

Company: Clinipad Corporation¹
Products: “urgent” recall of povidone-iodine, alcohol and other sterile products
Contaminant: Bacteria

2011

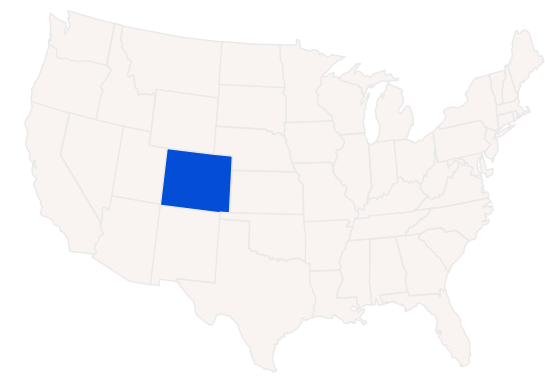
Company: Triad Group²
Products: alcohol prep pads, alcohol swabs and alcohol swabsticks
Contaminant: *Bacillus cereus*

Company: PDI³
Products: alcohol prep pads
Contaminant: *Bacillus cereus*

2016

Company: Sage Products⁴
Products: impregnated cloth topical skin products, including 2% chlorhexidine gluconate (CHG) cloths
Contaminant: *Burkholderia cepacia*

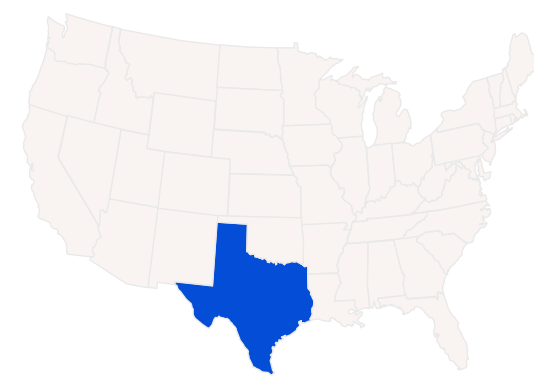
Triad recall set off the alarm



Aurora, Colorado¹

October-November 2010

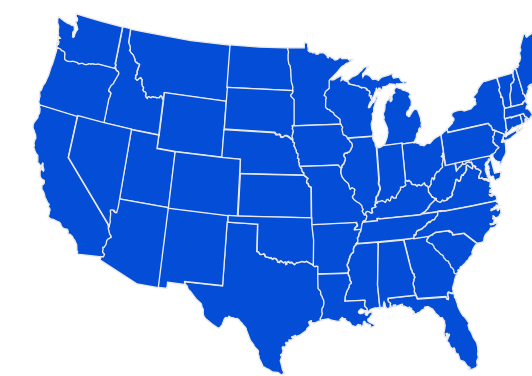
2 pediatric patients in The Children's Hospital developed clinical sepsis from *B cereus* infection following placement of a vascular access device in 1 case and an internal jugular line in the other. Triad alcohol prep pads were cultured as part of the hospital's investigation into these infections; 40 of 60 were contaminated with *Bacillus cereus* or *Bacillus spp*



Houston, Texas²

December 2010

2-year-old boy died of bacterial meningitis from *B cereus* infection following surgery; Triad alcohol wipes were the suspected cause of infection



Nationwide³

January 2011

Triad recalled alcohol prep products "due to potential contamination of these products with the bacteria *Bacillus cereus*, which could lead to life-threatening infections"

The FDA took action

2012: FDA held public hearing¹

Purpose: “To obtain input on how to address microbial contamination [of] patient preoperative skin preparation drug products”

Attendees:

- Panelists: FDA, CDC and CMS experts
- Speakers: healthcare professionals and antiseptic manufacturers

Reason:

“[T]he agency has received reports of contaminated patient preoperative skin preparations, which has led to a number of product recalls. And this raises a significant public health concern.¹”

— Scott Furness

Director of the Division of Non-Prescription Regulation
Development, Office of Drug
Evaluation, FDA CDER

The FDA followed through

2013: FDA issued Drug Safety Communication¹

Requested that manufacturers of preoperative and preinjection skin preparation antiseptics:

- Package products in single-use containers to reduce the risk of extrinsic contamination and infection
- Label antiseptic solutions as sterile or nonsterile so healthcare professionals can make informed decisions

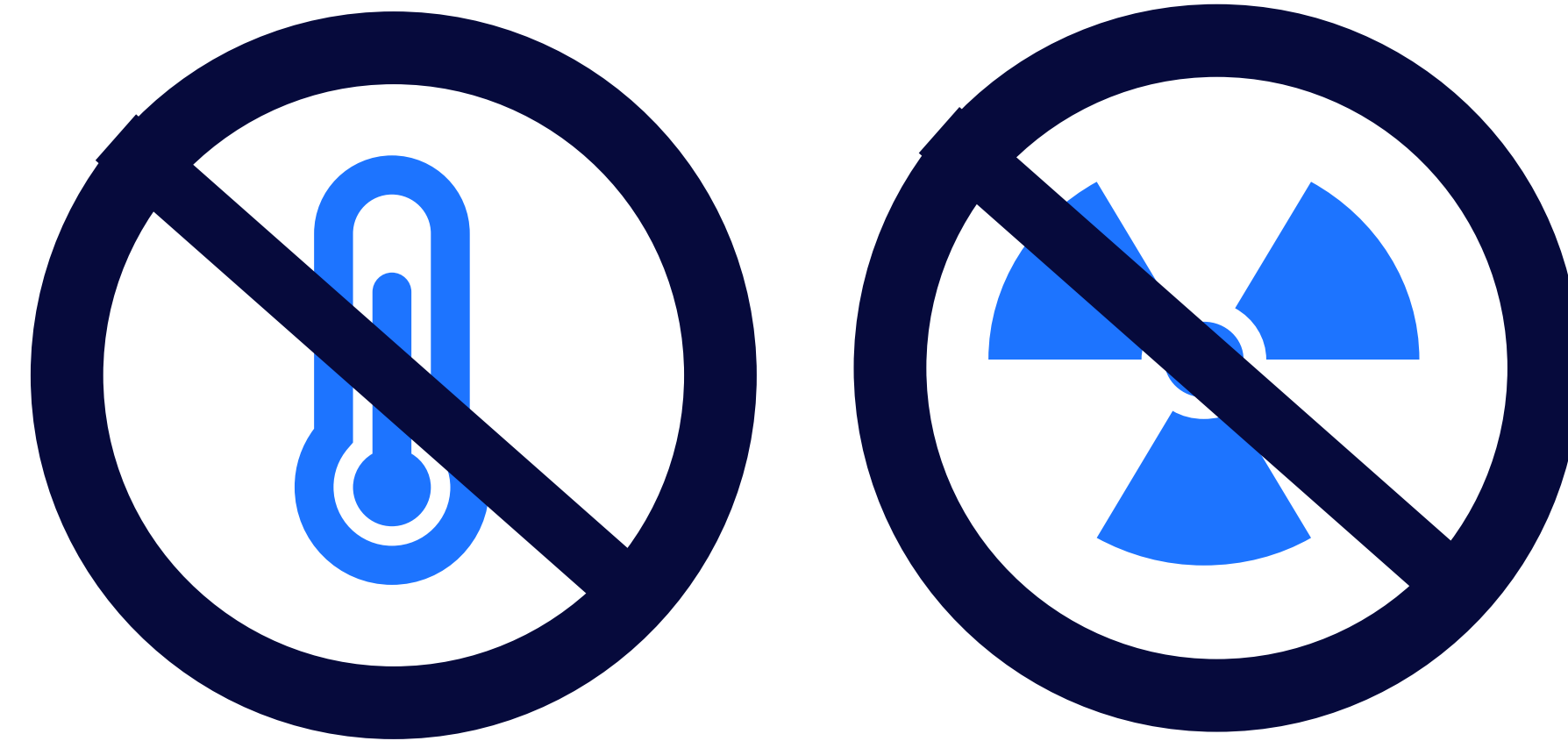
“Labeling stating a product is sterile means it was treated with a process during manufacturing to eliminate all potential microorganisms.¹”
- FDA Drug Safety Communication

BD: Going beyond
what is required to
do what is right

Sterilizing antiseptic solutions is a difficult challenge

Some manufacturers have asserted that it is “impossible or impractical”¹

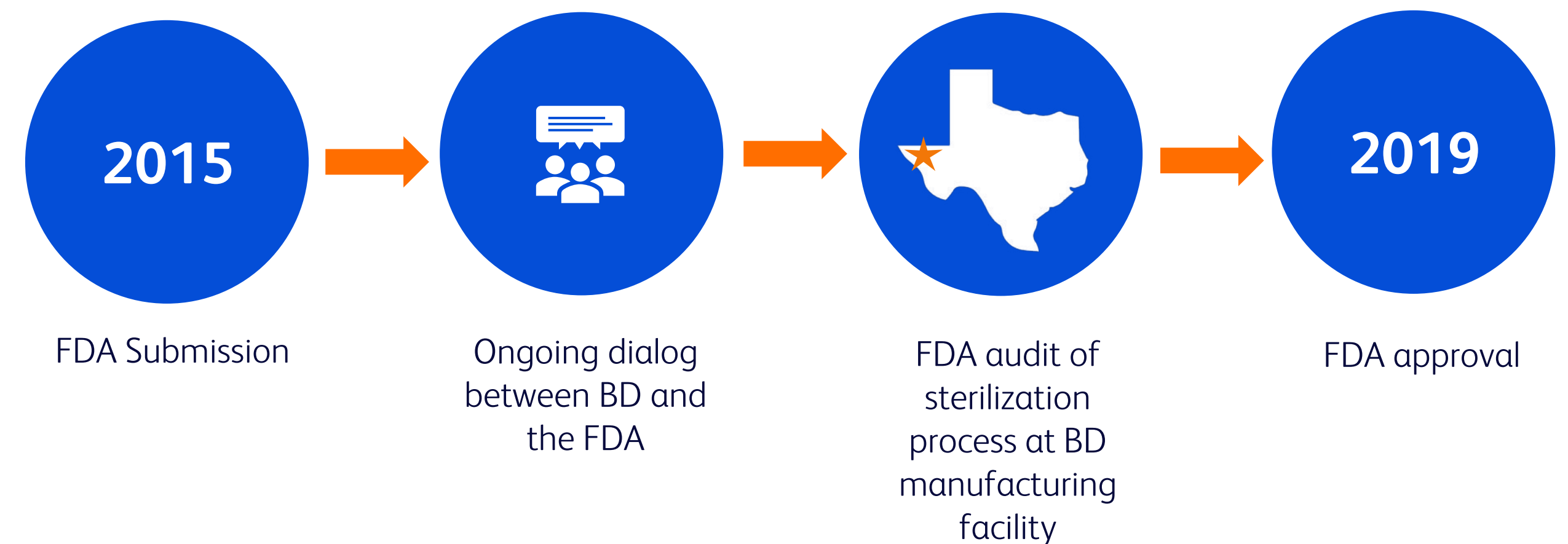
- Conventional terminal sterilization processes such as high heat and radiation are not compatible with common antiseptics, including CHG and can damage the chemical integrity of the active ingredient^{1,2}



BD overcame the “impossible”¹

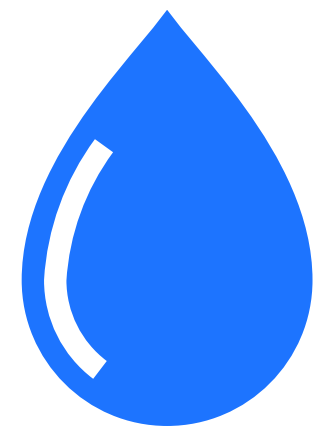
- BD ChloroPrep™ patient preoperative skin preparation has not been previously associated with outbreaks from intrinsic contamination
- Nonetheless, BD developed a new, proprietary sterilization technology
- The result? **The only commercially available CHG-based, sterile solution skin preparation in the United States**
- Offers the lowest risk of intrinsic contamination available in the US

Bringing BD ChloroPrep™ patient preoperative skin preparation with sterile solution to market



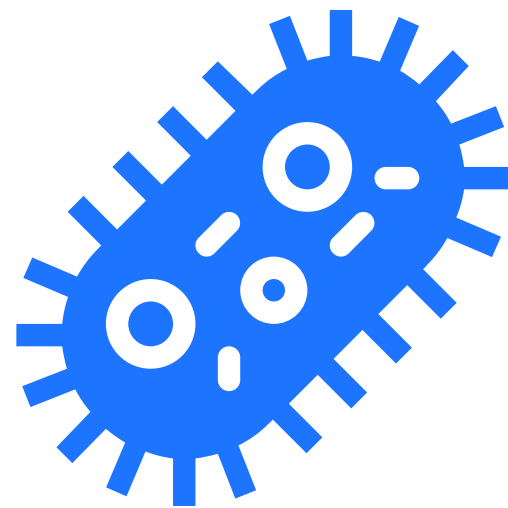
Minimizes the risk of intrinsic bacterial threats

Maintains the efficacy
and purity



of the antiseptic
solution¹

Less than a
1 in a million chance



Chance that a viable
microorganism can exist in a
BD ChloroPrep™ applicator¹

Sterility assurance level
of 10^{-6}



—the same level required
for injectable products¹

The commitment behind the achievement...



...because BD puts patient safety first

A continuing commitment

New sterilization technology is the latest BD innovation designed to advance skin antiseptics

Prior innovations for BD ChloroPrep™ patient preoperative skin preparation include:



5 applicator sizes for a wide range of coverage areas



New tints for various skin tones



Improved Frepp™ design for increased safety



Conversion of Sepp to 1 mL applicator for easier use and increased volume

Elevating the standard in preoperative skin antisepsis

A comparison of patient preoperative skin antiseptics

	Alcohol	Iodophors (iodine-based)	CHG	Iodine + alcohol	BD PurPrep™ patient preoperative skin preparation with sterile solution	CHG + alcohol	BD ChlorPrep™ patient preoperative skin preparation with sterile solution
Broad spectrum ¹⁻⁴	x	x	x	x	x	x	x
Fast acting ¹⁻⁴	x			x	x	x	x
Persistent ¹⁻⁴			x	x	x	x	x
Acting in the presence of organic matter ¹⁻⁴			x			x	x
Minimizes the risk of intrinsic contamination					x		x

Providing peace of mind for clinicians and patients

BD ChloraPrep™ patient preoperative skin preparation:



Trusted by hospitals
for more than
21 years



Supported by
more than
**50 peer-reviewed
publications**



>5 billion
applicators used

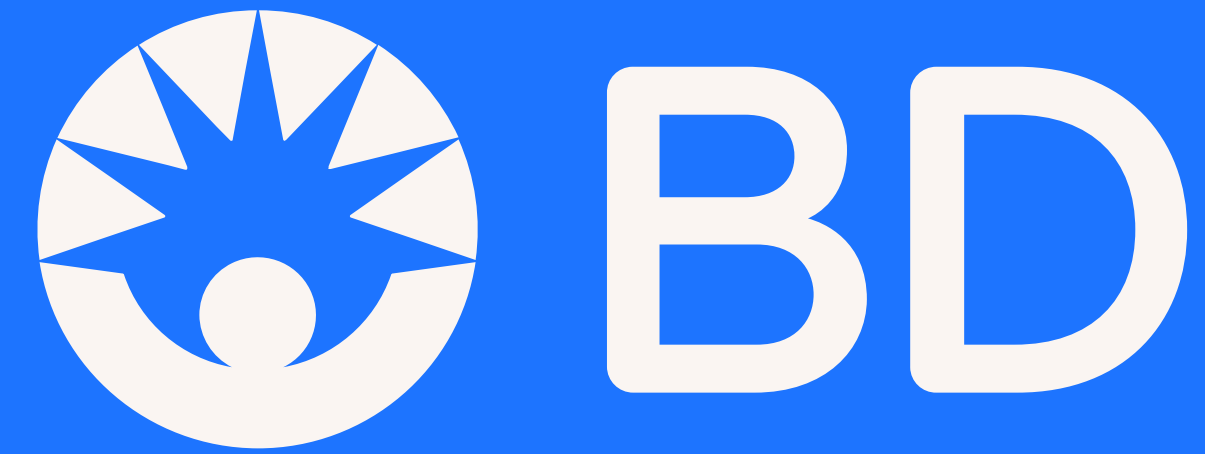
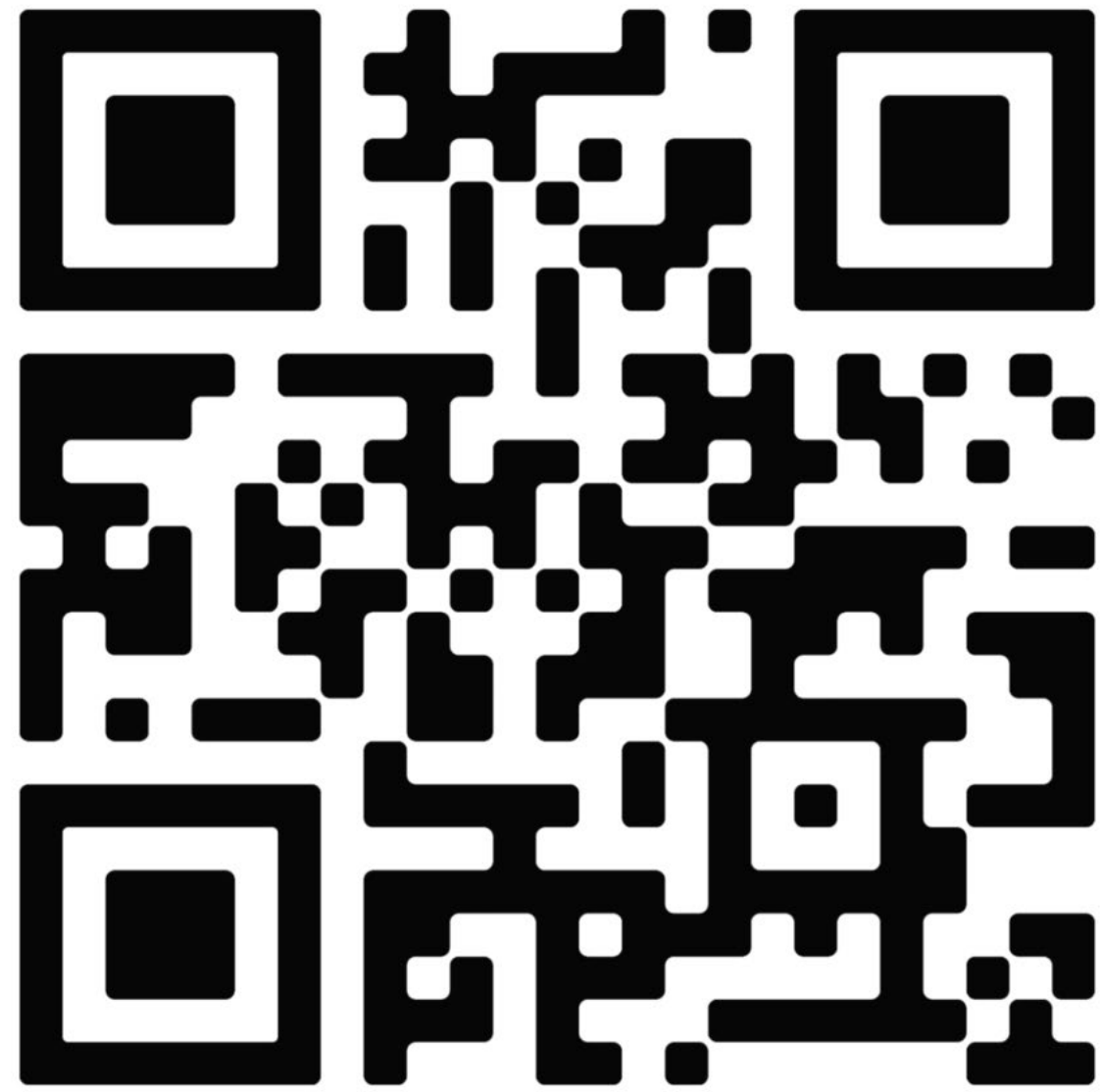
With FDA-approved BD ChloraPrep™ patient preoperative skin preparation with sterile solution, BD has achieved a new benchmark in skin antisepsis

Now offering the first and only portfolio of fully sterile preoperative skin prep applicator products

A comparison of patient preoperative skin antiseptics

Attribute	BD Chloraprep™ patient preoperative skin preparation with Sterile Solution	BD PurPrep™ patient preoperative skin preparation with Sterile Solution.
Applicator	Proprietary single-use sterile applicator	Proprietary single-use sterile applicator
Formula	Chlorhexidine gluconate (CHG) + Isopropyl Alcohol	Povidone Iodine and Isopropyl Alcohol
Sterile Solution	✓	✓
Dry surgical site application repeated back-and-forth strokes for 30 seconds	✓	✓
Moist surgical site application: repeated back-and-forth strokes for 2 minutes	✓	✓
Use	For 18 years has been used for the preparation of patients' skin prior to surgery	<p>An alternative choice for the preparation of the patient's skin prior to the surgery when a CHG and Isopropyl Alcohol– containing product is not an option:</p> <ul style="list-style-type: none"> • Patients allergic to CHG • Clinical procedures/ scenarios in which CHG is contraindicated

Scan code to learn more



Thank You

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