

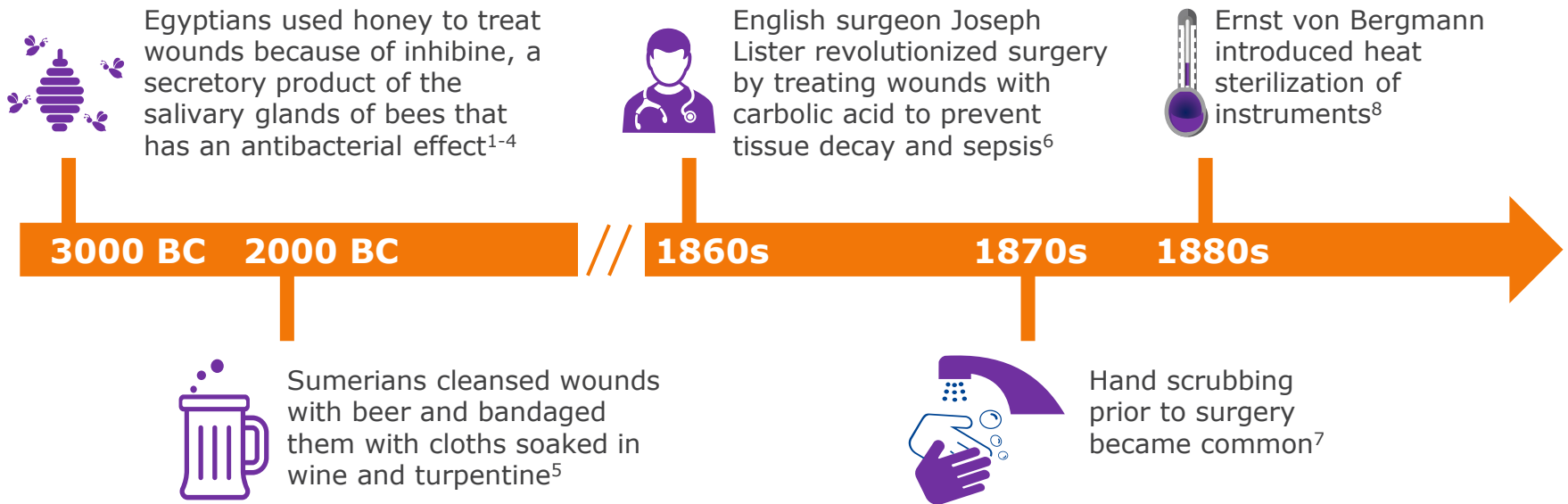


# Elevating the standard

NEW BD ChloraPrep™ patient preoperative skin preparation with sterile solution

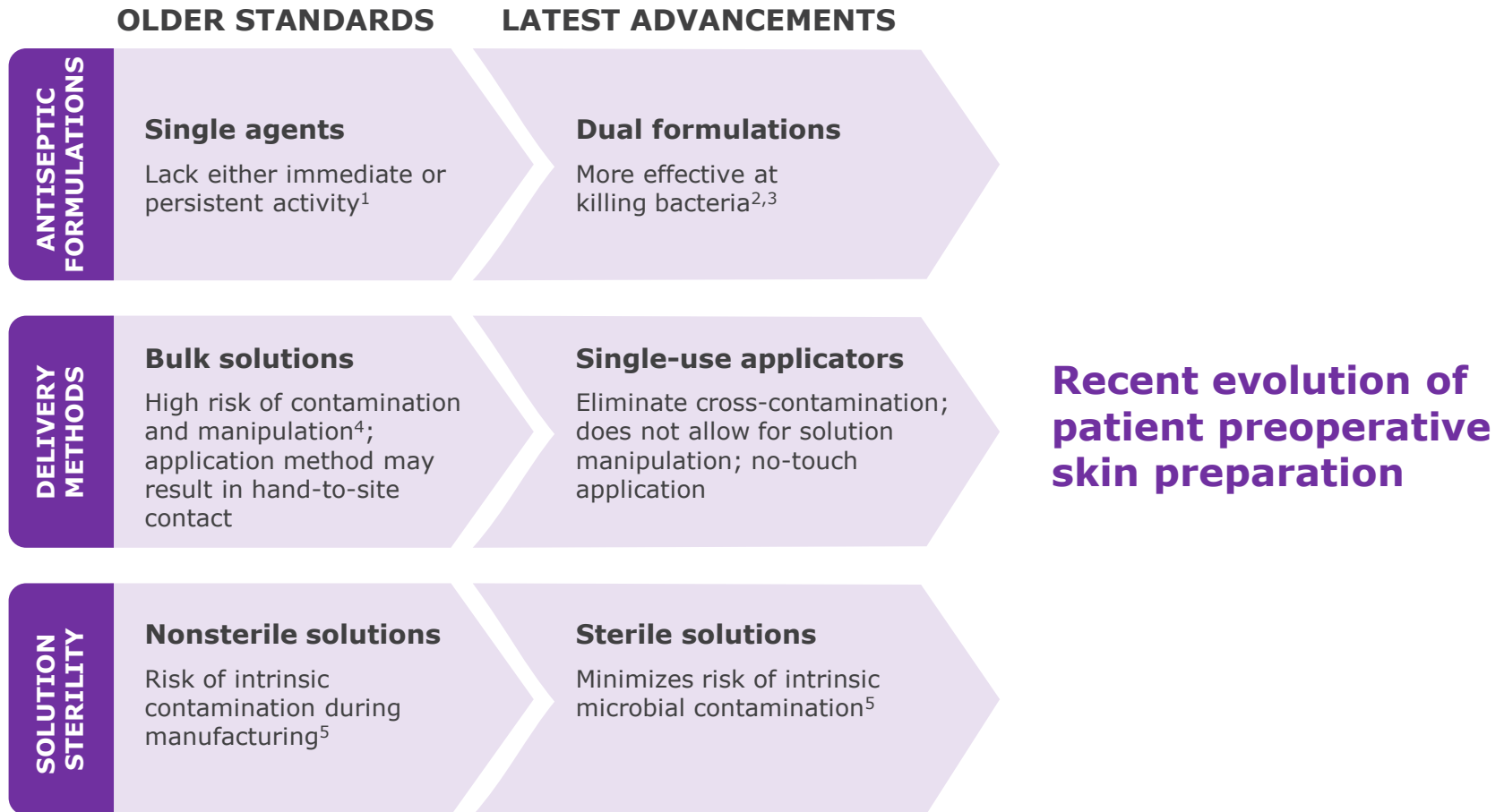


# Antisepsis has evolved



**1** Treadwell T. <https://www.woundsresearch.com/article/7749>. Accessed July 11, 2019. **2** Tehuti Research Foundation. <https://egypt-tehuti.org/learned-ancient-egyptians/the-advanced-egyptian-medical-library/>. Accessed April 28, 2019. **3** White JW Jr, et al. *Biochimica et Biophysica Acta*. 1963;73:57-70. **4** Enany S, Crotty Alexander LE, eds. *Frontiers in Staphylococcus aureus*; chapter 10, by Szweda P, Kot B (<http://dx.doi.org/10.5772/65978>). 2017. ISBN 978-953-51-2981-3. **5** McDonnell G, Sheard D. *A Practical Guide to Decontamination in Healthcare*. 2012. ISBN 978-1-4443-3013-7. **6** Pitt D, et al. *Can J Surg*. 2012;55(5):E8-E9. **7** Smithsonian.com. <https://www.smithsonianmag.com/smart-news/idea-sterilizing-surgical-instruments-only-150-years-old-180962498/>. Accessed July 11, 2019. **8** Church JR, ed. *The Military Surgeon: Journal of the Association of Military Surgeons of the United States* 1922;50(1).

# Important advances continue to be made



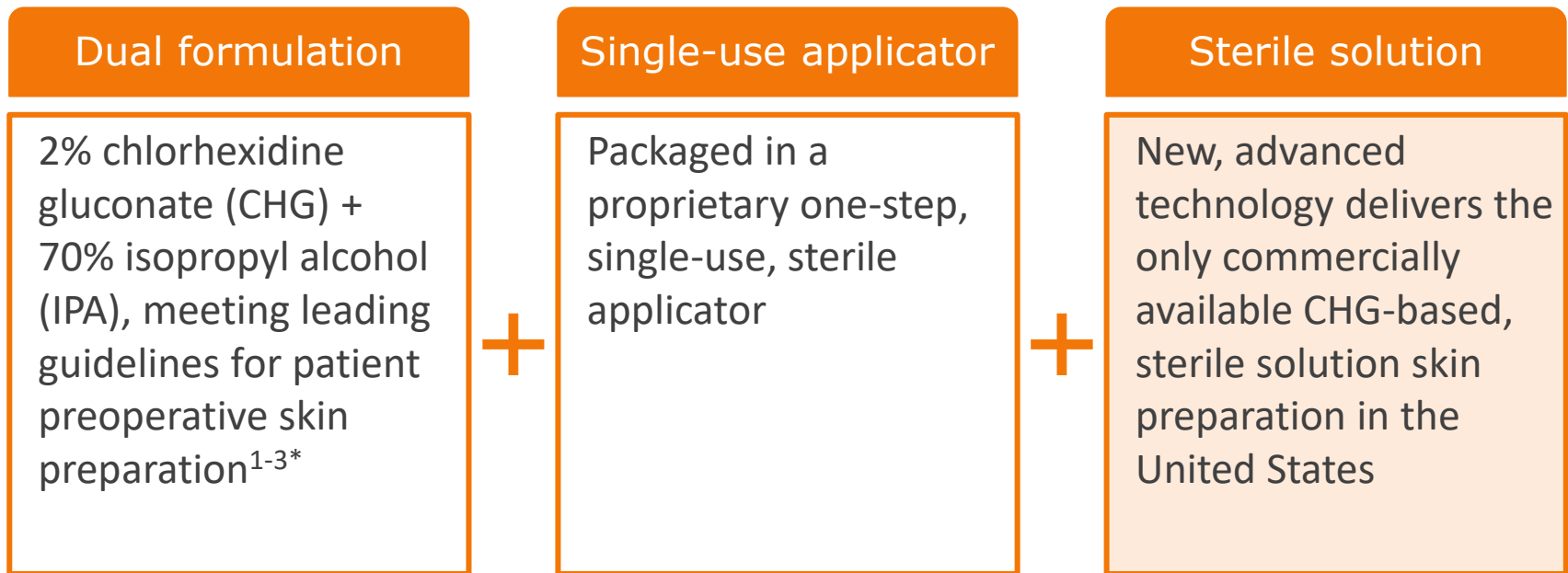
<sup>1</sup> Hemani ML, et al. *Rev Urol.* 2009;11(4):190-195. doi: 10.3909/riu0467. <sup>2</sup> Ostrander RV, et al. *J Bone Joint Surg Am.* 2005;87(5):980-985. <sup>3</sup> Saltzman MD, et al. *J Bone Joint Surg Am.* 2009;91(8):1949-1953. <sup>4</sup> Association of periOperative Registered Nurses. In: *Guidelines for Perioperative Practice.* Denver, CO: AORN, Inc; 2016. <sup>5</sup> Food and Drug Administration. <https://www.fda.gov/drugs/drugsafety/ucm374711.htm>. Accessed March 19, 2019.

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# BD: At the forefront of the antiseptic evolution

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



\*Guidelines from the World Health Organization (WHO), American College of Surgeons/Surgical Infection Society, and Centers for Disease Control and Prevention recommend alcohol-based patient preoperative skin preparations; WHO recommends a CHG + alcohol solution.

**1** World Health Organization. Global guidelines for the prevention of surgical site infection. Geneva, Switzerland. 2016. **2** Ban K, et al. *J Am Coll Surg.* 2017; <http://dx.doi.org/10.1016/j.jamcollsurg.2016.10.029>. **3** Berrios-Torres SI, et al. *JAMA Surg.* 2017;152(8):784-791. doi:10.1001/jamasurg.2017.0904.

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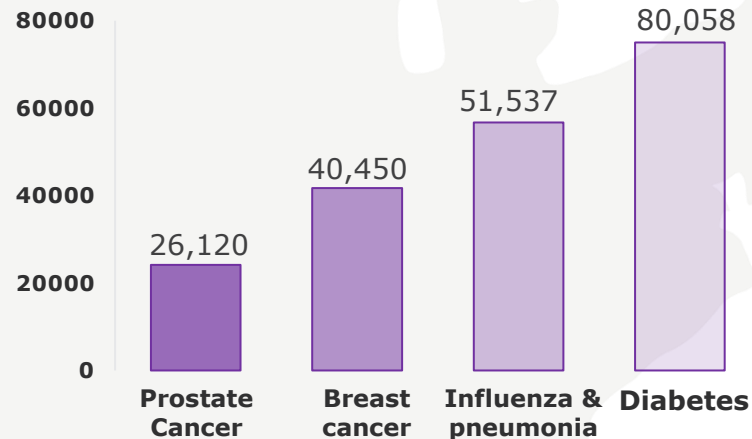
# Why sterilize?

# Healthcare associated infections (HAIs) are a major threat

**72,000 deaths**  
in 2015 in the United States due to HAIs<sup>1</sup>

**\$9.8 billion**  
in associated annual US healthcare costs<sup>2</sup>

**Approximate deaths/year in the United States (2016)<sup>3,4</sup>**

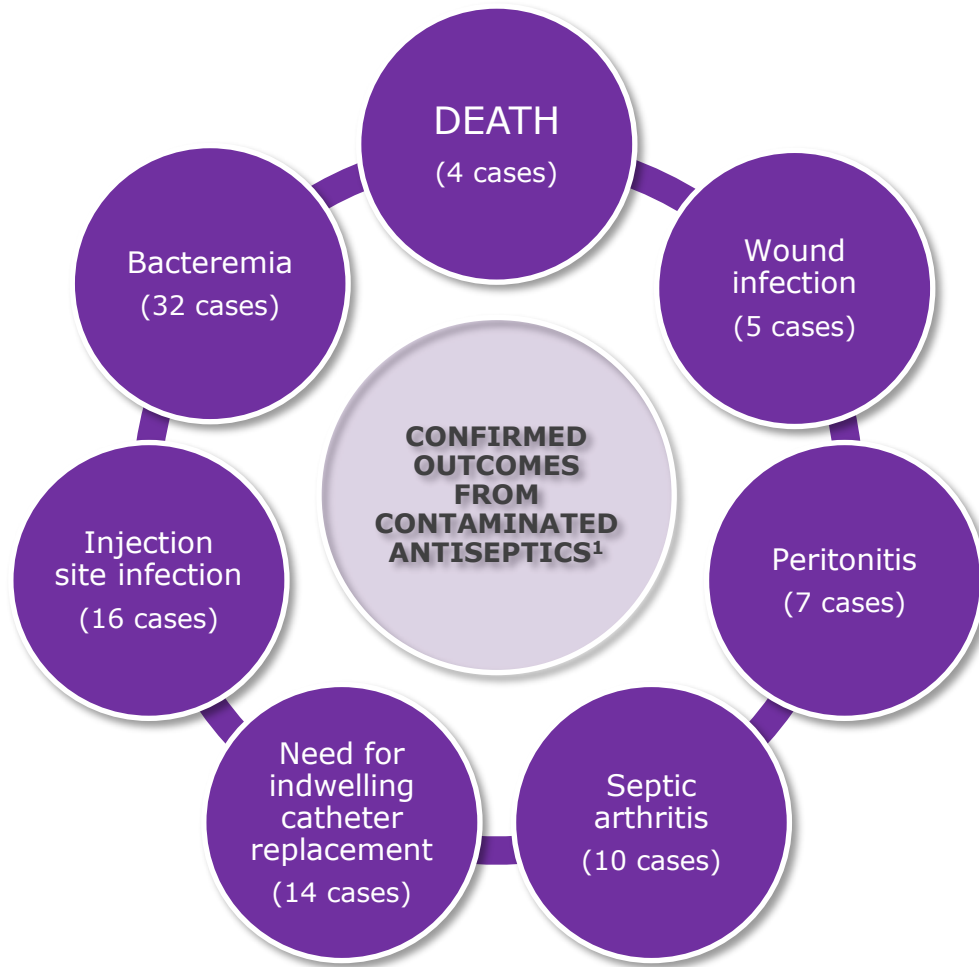


<sup>1</sup> Centers for Disease Control and Prevention. <https://www.cdc.gov/hai/data/portal/index.html>. Accessed May 20, 2019.

<sup>2</sup> Zimlichman E, Henderson D, Tamir O, et al. Health-care associated infections: a meta-analysis of costs and financial impact on the US health care system. *JAMA Intern Med.* 2013;173(22):2039-2046; <sup>3</sup> [https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67\\_05.pdf](https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_05.pdf)

<sup>4</sup> <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2016/cancer-facts-and-figures-2016.pdf>

# Contaminated antiseptics are a documented cause of HAIs



**Outcomes may be underreported for a range of reasons, including<sup>2</sup>**

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

<sup>1</sup> Food and Drug Administration. <https://www.fda.gov/drugs/drugsafety/ucm374711.htm>. Accessed March 19, 2019. <sup>2</sup> Chang CY, et al. *N Engl J Med.* 2012;367(23):2170-2173.

# 2 mechanisms are responsible

**Extrinsic contamination:** end-user based; can result from<sup>1</sup>:



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 to<sup>1</sup>:



Contaminated pharmaceutical water supply



Nonsterile manufacturing environment

<sup>1</sup> Food and Drug Administration. <https://www.fda.gov/drugs/drugsafety/ucm374711.htm>. Accessed March 19, 2019.



# Intrinsic contamination has prompted product recalls

**Company:** Clinipad Corporation<sup>1</sup>

**Products:** “urgent” recall of povidone-iodine, alcohol and other sterile products

**Contaminant:** Bacteria

2000

2011

2016

**Company:** Sage Products<sup>4</sup>

**Products:** impregnated cloth topical skin products, including 2% chlorhexidine gluconate (CHG) cloths

**Contaminant:**  
*Burkholderia cepacia*

**Company:** Triad Group<sup>2</sup>

**Products:** alcohol prep pads, alcohol swabs and alcohol swabsticks

**Contaminant:** *Bacillus cereus*

**Company:** PDI<sup>3</sup>

**Products:** alcohol prep pads

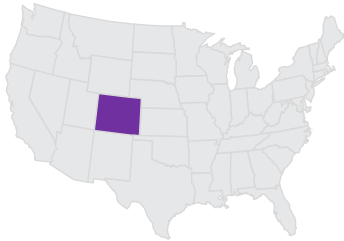
**Contaminant:** *Bacillus cereus*

<sup>1</sup> Infection Control Today. <https://www.infectioncontroltoday.com/print/24691>. Accessed May 3, 2019. <sup>2</sup> FDA. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=100988>. Accessed December 17, 2017. <sup>3</sup> FDA. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=105181>. <sup>4</sup> FDA. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sage-products-expands-voluntary-worldwide-recall-specific-lots-topical-skin-products-due-potential>. Accessed May 3, 2019.

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# Triad recall set off the alarm



## Aurora, Colorado<sup>1</sup>

**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

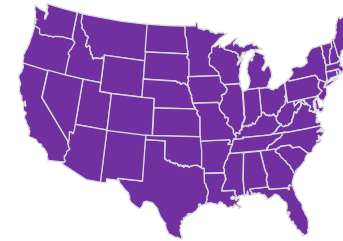
Triad alcohol prep pads were cultured as part of the hospital's investigation into these infections; 40 of 60 were contaminated with *Bacillus cereus* or *Bacillus spp*



## Houston, Texas<sup>2</sup>

**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



## Nationwide<sup>3</sup>

**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"

<sup>1</sup> Dolan SA, et al. *CDC Morbidity and Mortality Weekly Report*. 2011;60(11):347. <sup>2</sup> [http://vitals.nbcnews.com/\\_news/2012/12/05/15702729-bacteria-in-antiseptic-skin-prep-fda-ponders-sterility?lite](http://vitals.nbcnews.com/_news/2012/12/05/15702729-bacteria-in-antiseptic-skin-prep-fda-ponders-sterility?lite). Accessed May 6, 2019. <sup>3</sup> Food and Drug Administration. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=100988>

# The FDA took action

## 2012: FDA held public hearing<sup>1</sup>

**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.<sup>1</sup>

— Scott Furness

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

”

<sup>1</sup> Food and Drug Administration Center for Drug Evaluation and Research Department of Health and Human Services. Docket No. FDA-2012-N-1040.

# The FDA followed through

## 2013: FDA issued Drug Safety Communication<sup>1</sup>

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.<sup>1</sup>

- FDA Drug Safety Communication

”

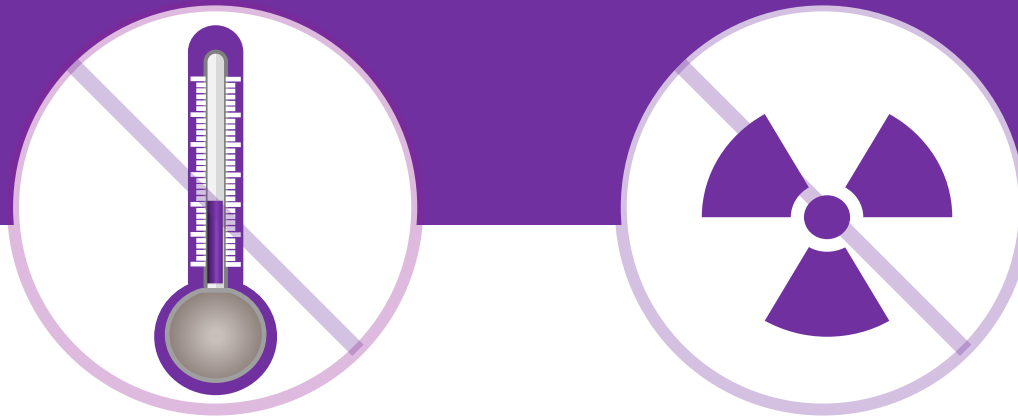
<sup>1</sup> Food and Drug Administration. <https://www.fda.gov/drugs/drugsafety/ucm374711.htm>. Accessed March 19, 2019.

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”<sup>1</sup>

- 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<sup>1,2</sup>

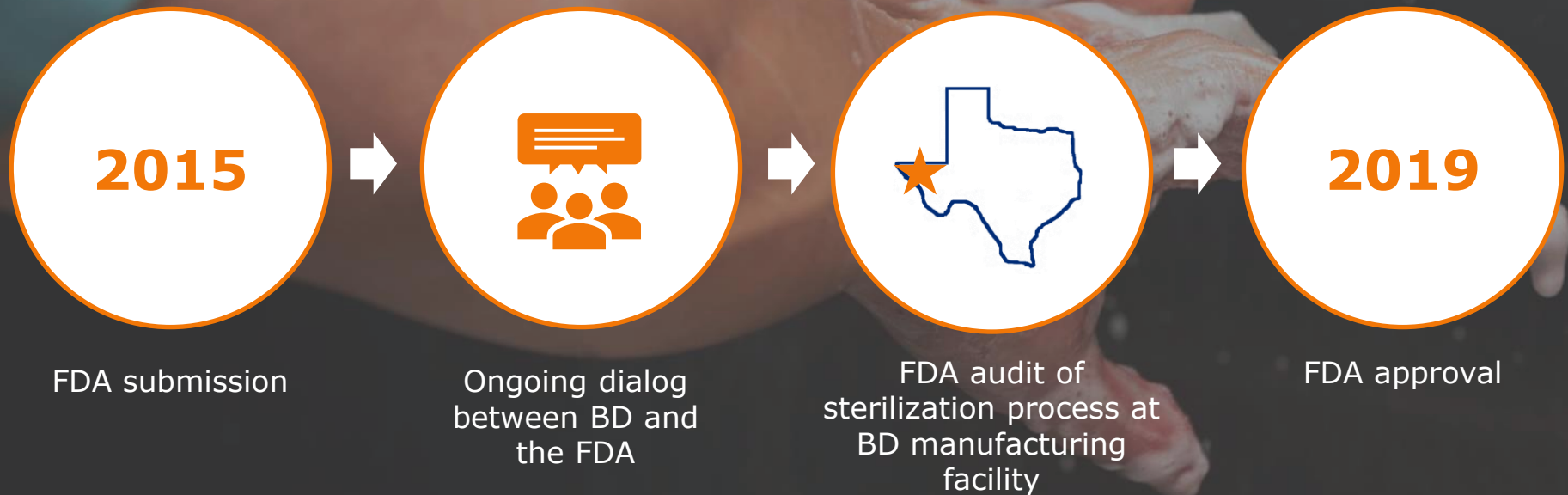


<sup>1</sup> Pyrek KM. *Infection Control Today*. 2013;July:1-30. <https://brnskill.com/wp-content/uploads/2013/12/FDA-investigates-Antiseptics-Sterility-and-potential-recommendations.pdf>. Accessed April 20, 2019. <sup>2</sup> **Denton: See chapter pub**

# BD overcame the “impossible”<sup>1</sup>

- 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



<sup>1</sup> Pyrek KM. Sterility of antiseptic products: FDA investigates, deliberates on potential recommendations. *Infection Control Today*. 2013;July:1-30. <https://brnskill>.

# Minimizes the risk of intrinsic bacterial threats

**Maintains the efficacy and purity**



of the antiseptic solution<sup>1</sup>

Less than a  
**1 in a million chance**



chance that a viable microorganism can exist in a BD ChloraPrep™ applicator<sup>1</sup>

**Sterility assurance level of 10<sup>-6</sup>**

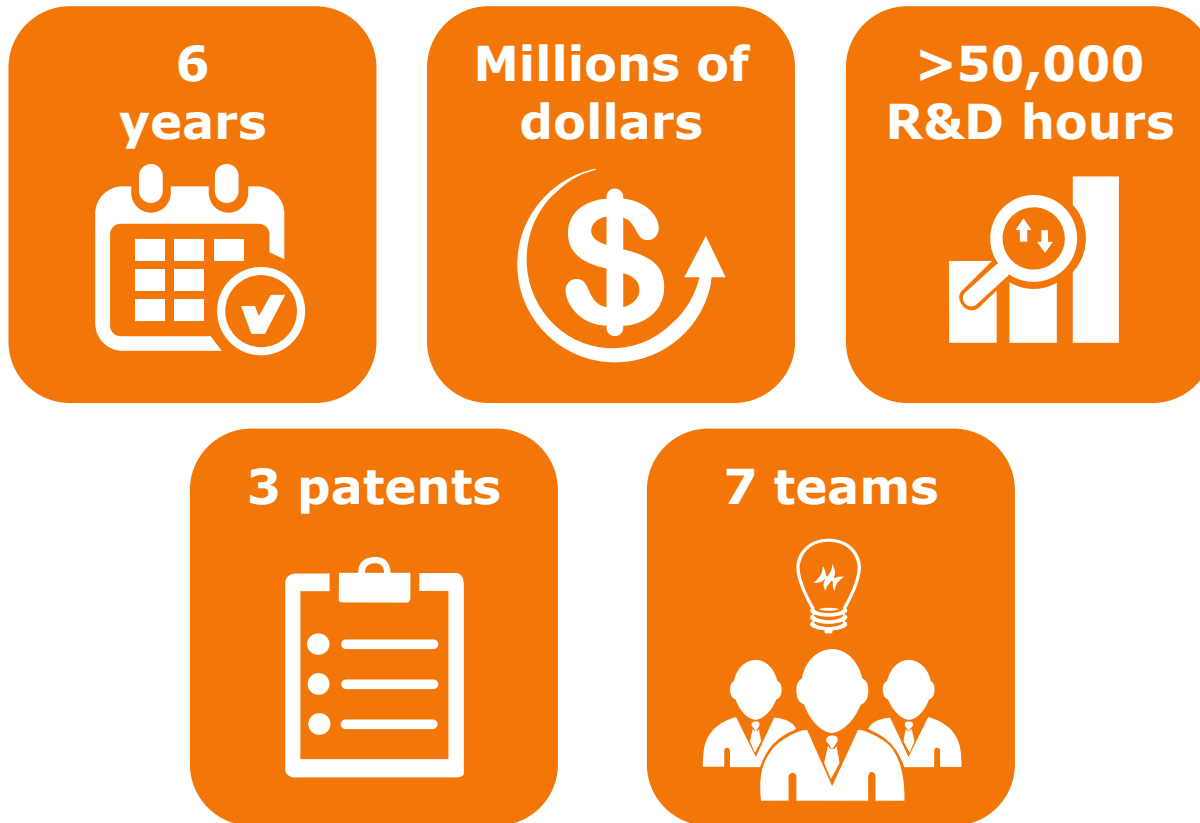


—the same level required for injectable products<sup>1</sup>

<sup>1</sup> Degala, et al. United States Patent 9,078,934. July 14, 2015.



# The commitment behind the achievement...



**...because BD puts patient safety first**

# A continuing commitment

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

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



**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	CHG + alcohol	BD ChloroPrep™ patient preoperative skin preparation with sterile solution
<b>Broad spectrum<sup>1-4</sup></b>	x	x	x	x	x	x
<b>Fast acting<sup>1-4</sup></b>	x			x	x	x
<b>Persistent<sup>1-4</sup></b>			x	x	x	x
<b>Acting in the presence or organic matter<sup>1-4</sup></b>			x		x	x
<b>Minimizes the risk of intrinsic contamination</b>						x

**1** Mangram AJ, et al. *Infect Control Hosp Epidemiol.* 1999;20(4):247-278. **2** AORN. Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc.; 2013:75-89. **3** Galvin P. *Am J Nurs.* 2009;109(12):49-55. doi: 10.1097/01.NAJ.0000365187.47124.c0. **4** Karpanen TJ, et al. *Antimicrob Agents Chemother.* 2009;53(4):1717-1719. doi:10.1128/AAC.01289-08.

# Providing peace of mind for clinicians and patients

## BD ChloroPrep™ patient preoperative skin preparation:



Trusted by hospitals  
for more than

**18 years**



Supported by  
more than

**50 peer-reviewed  
publications**



**>4 billion**  
applicators used

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

# The logistics of change

- **New name**  
BD ChloroPrep™ patient preoperative skin preparation with sterile solution
- **New addition to package label**  
“Sterile Solution” will be on all packaging
- **New BD branding**
- **New sterile product estimated availability**



# The logistics of change

Applicator	Old SKU	New SKU
Single swabstick 1.75 mL	260100	No change
Triple swabstick 5.25 mL	260103	No change
1 mL clear	260480	930480
FREPP™ 1.5 mL clear	260299	930299
3 mL clear	260400	930400
3 mL Hi-Lite Orange™	260415	930415
10.5 mL clear	260700	930700
10.5 mL Hi-Lite Orange™	260715	930715
10.5 mL Scrub Teal™	260725	930725
26 mL clear	260800	930800
26 mL Hi-Lite Orange™	260815	930815
26 mL Scrub Teal™	260825	930825

# Impact on pricing

- Over the past 5 years, BD invested millions of dollars and over 50,000 hours of R&D time to create this proprietary and patented sterility process
- We reached this milestone ahead of clinical guidelines, mandates and regulation to further advance the field
- To ensure our ability to continue to provide seamless supply and innovations to support patient care, we are taking a slight price increase with our customers as we introduce BD ChloroPrep™ patient preoperative skin preparation with sterile solution

# Impact on Pricing

Placeholder – Working on getting Vizient examples.

System/Member	Annual Spend	Ar			
Providence Health	\$ 2,310,428	\$			
Providence Everett	\$ 23,293	\$	1,838	\$ 153	7.89%
Baylor S&W Health	\$ 1,489,708	\$	97,318	\$ 8,110	6.53%
BUMC	\$ 149,767	\$	7,982	\$ 665	5.33%
Yale New Haven Health	\$ 671,191	\$	39,504	\$ 3,292	5.89%
Greenich Hospital	\$ 38,207	\$	2,288	\$ 191	5.99%
NY Presbyterian Health	\$ 298,892	\$	13,349	\$ 1,112	4.47%
NY Presbyterian Hospital	\$ 66,186	\$	2,262	\$ 188	3.42%



**To learn more, visit**  
**[bd.com/ChloroPrepSterileSolution](https://bd.com/ChloroPrepSterileSolution)**



Thank you!

