

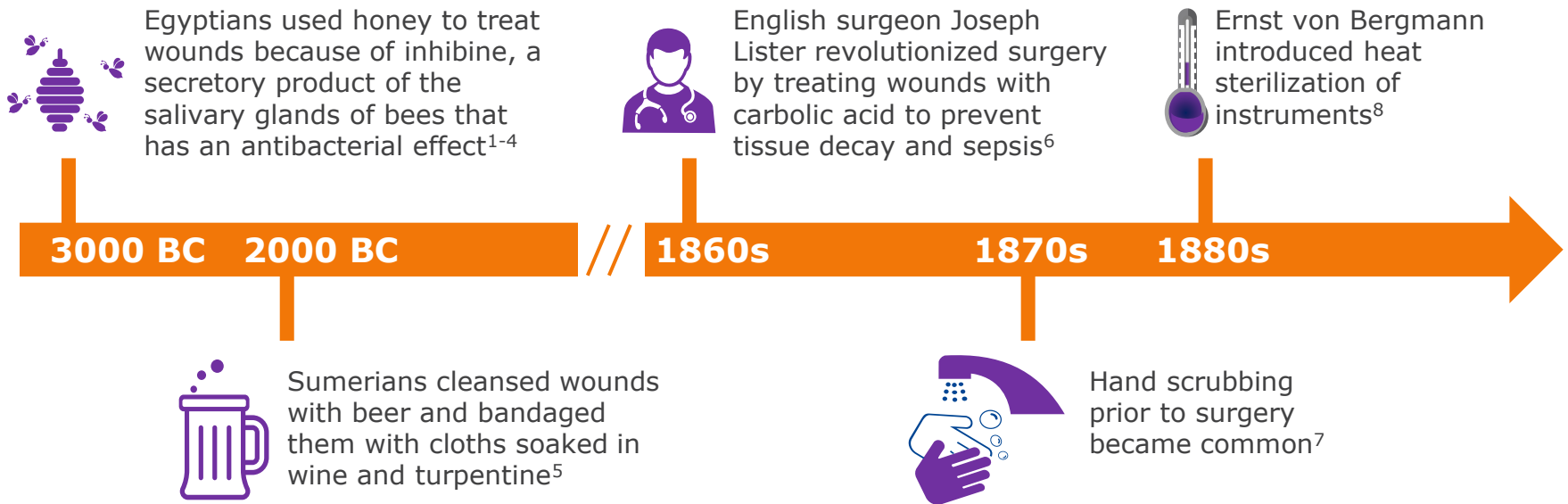


Elevating the standard

NEW BD ChloraPrep™ patient preoperative skin preparation with sterile solution

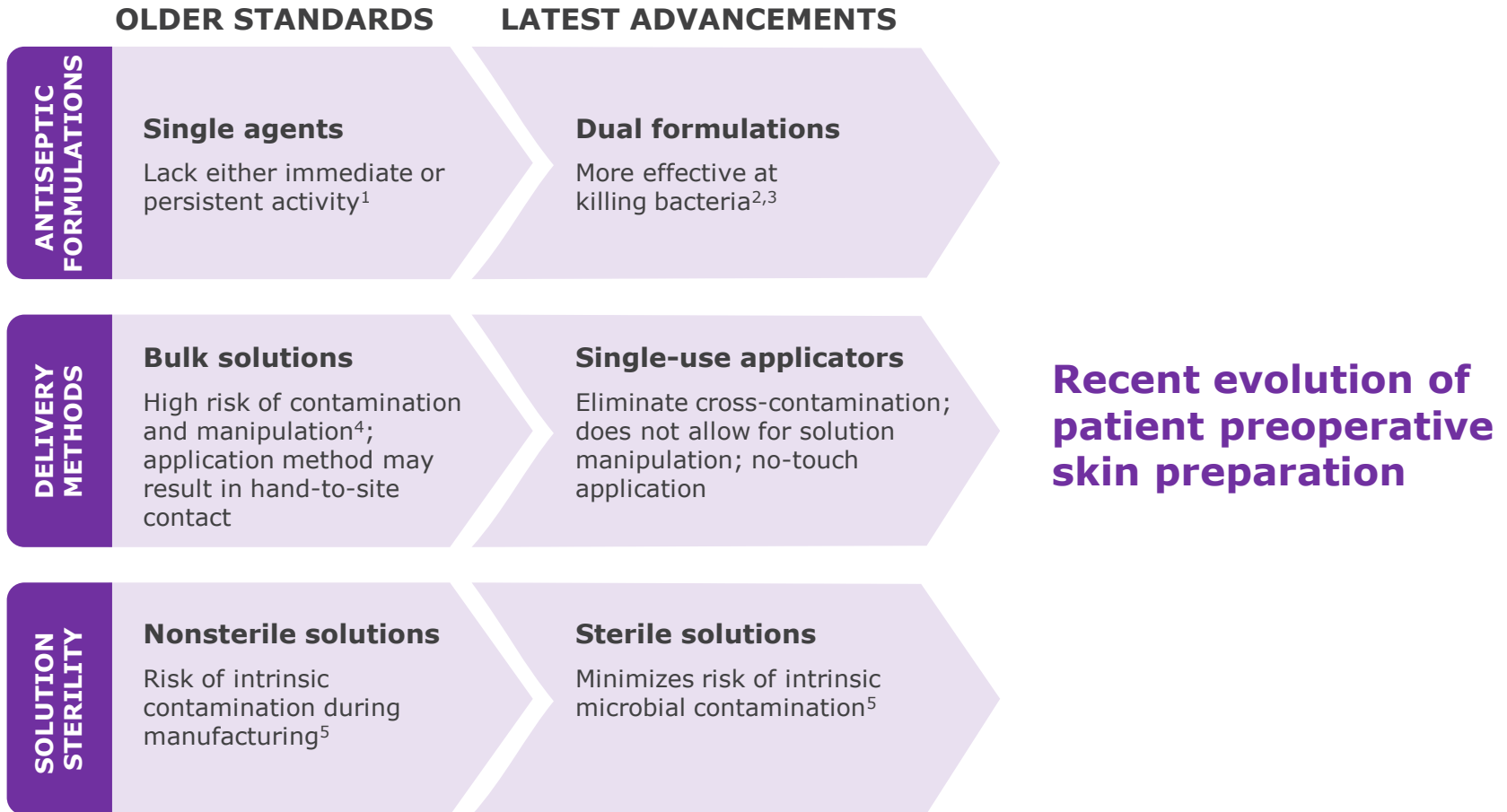


Antisepsis has evolved



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



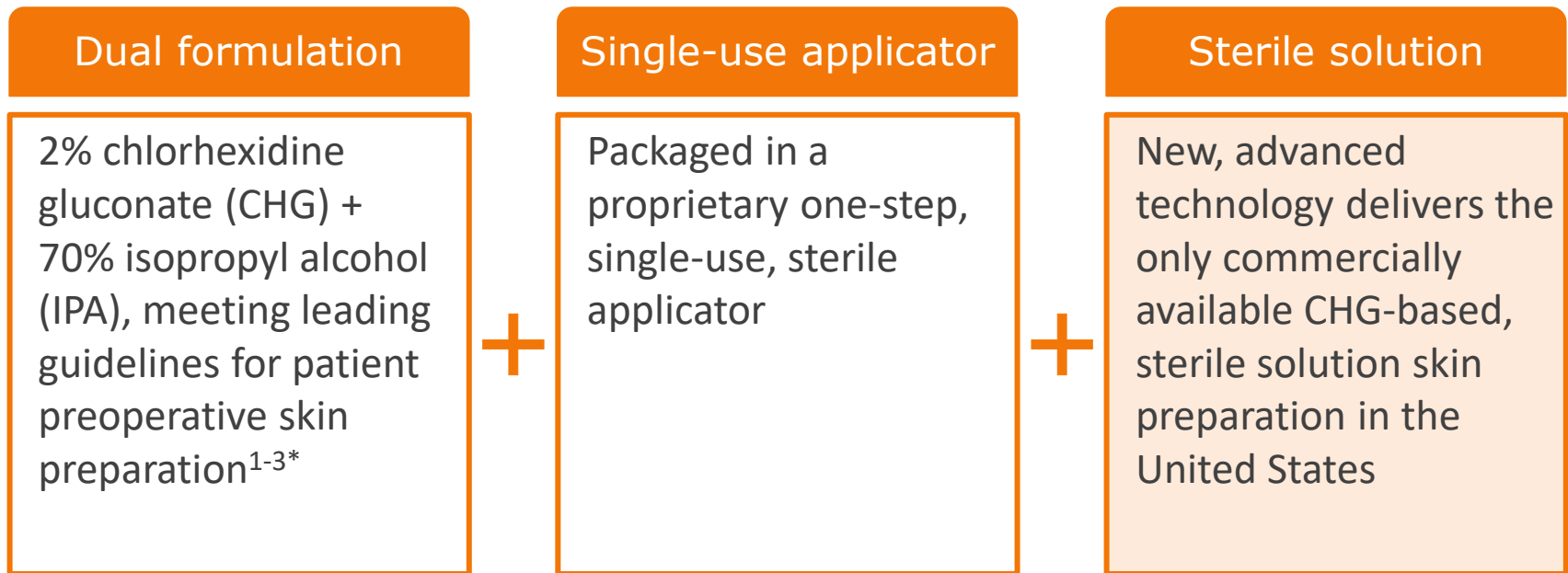
¹ Hemani ML, et al. *Rev Urol.* 2009;11(4):190-195. doi: 10.3909/riu0467. ² Ostrander RV, et al. *J Bone Joint Surg Am.* 2005;87(5):980-985. ³ Saltzman MD, et al. *J Bone Joint Surg Am.* 2009;91(8):1949-1953. ⁴ Association of periOperative Registered Nurses. In: *Guidelines for Perioperative Practice.* Denver, CO: AORN, Inc; 2016. ⁵ 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 ChloroPrep™ 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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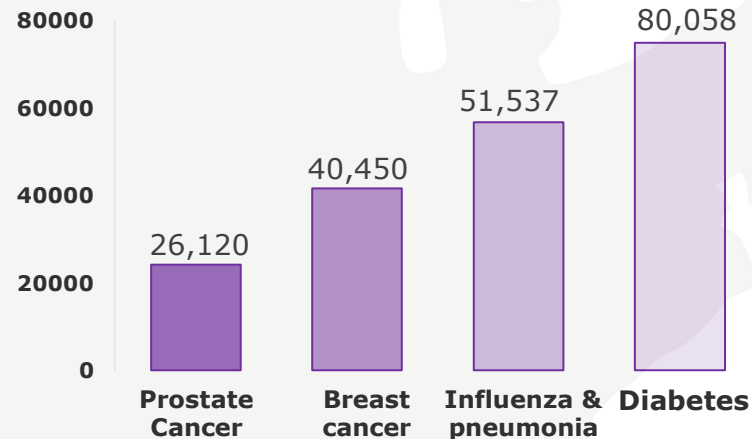
Why sterilize?

Healthcare associated infections (HAIs) are a major threat

72,000 deaths
in 2015 in the United States due to HAIs¹

\$9.8 billion
in associated annual US healthcare costs²

Approximate deaths/year in the United States (2016)^{3,4}

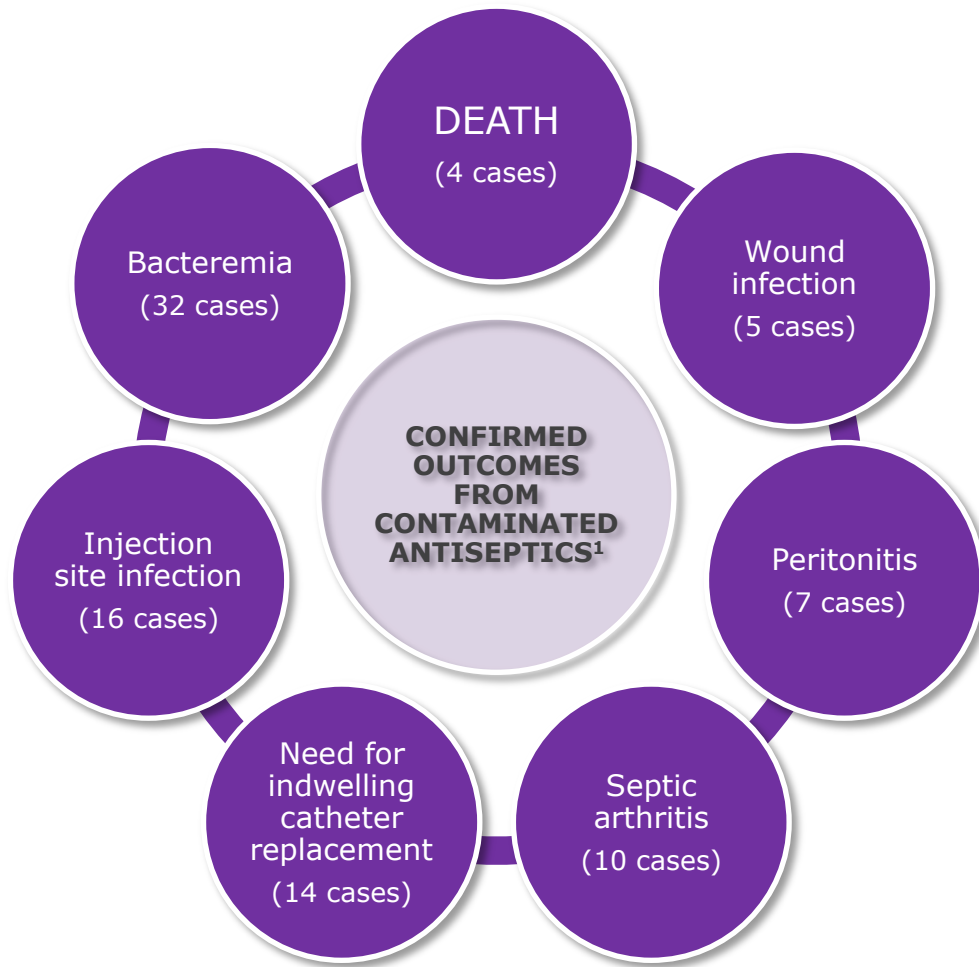


¹ Centers for Disease Control and Prevention. <https://www.cdc.gov/hai/data/portal/index.html>. Accessed May 20, 2019.

² 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; ³ https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_05.pdf

⁴ <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, including²

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

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

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

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

Intrinsic contamination has prompted product recalls

Company: Clinipad Corporation¹

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

Contaminant: Bacteria

2000

2011

2016

Company: Sage Products⁴

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

Contaminant:
Burkholderia cepacia

Company: Triad Group²

Products: alcohol prep pads, alcohol swabs and alcohol swabsticks

Contaminant: *Bacillus cereus*

Company: PDI³

Products: alcohol prep pads

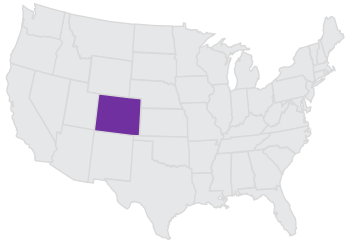
Contaminant: *Bacillus cereus*

¹ Infection Control Today. <https://www.infectioncontroltoday.com/print/24691>. Accessed May 3, 2019. ² FDA. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=100988>. Accessed December 17, 2017. ³ FDA. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=105181>. ⁴ 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, 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

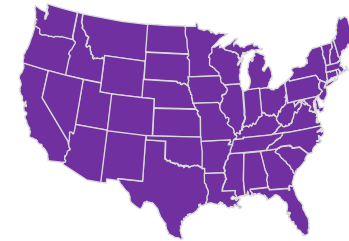
Triad alcohol prep pads were cultured as part of the hospital's investigation into these infections; 40 of 60 were contaminated with *Bacillus cereus* or *Bacillus spp*



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"

¹ Dolan SA, et al. *CDC Morbidity and Mortality Weekly Report*. 2011;60(11):347. ² http://vitals.nbcnews.com/_news/2012/12/05/15702729-bacteria-in-antiseptic-skin-prep-fda-ponders-sterility?lite. Accessed May 6, 2019. ³ 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 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

”

¹ 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 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

”

¹ 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”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}

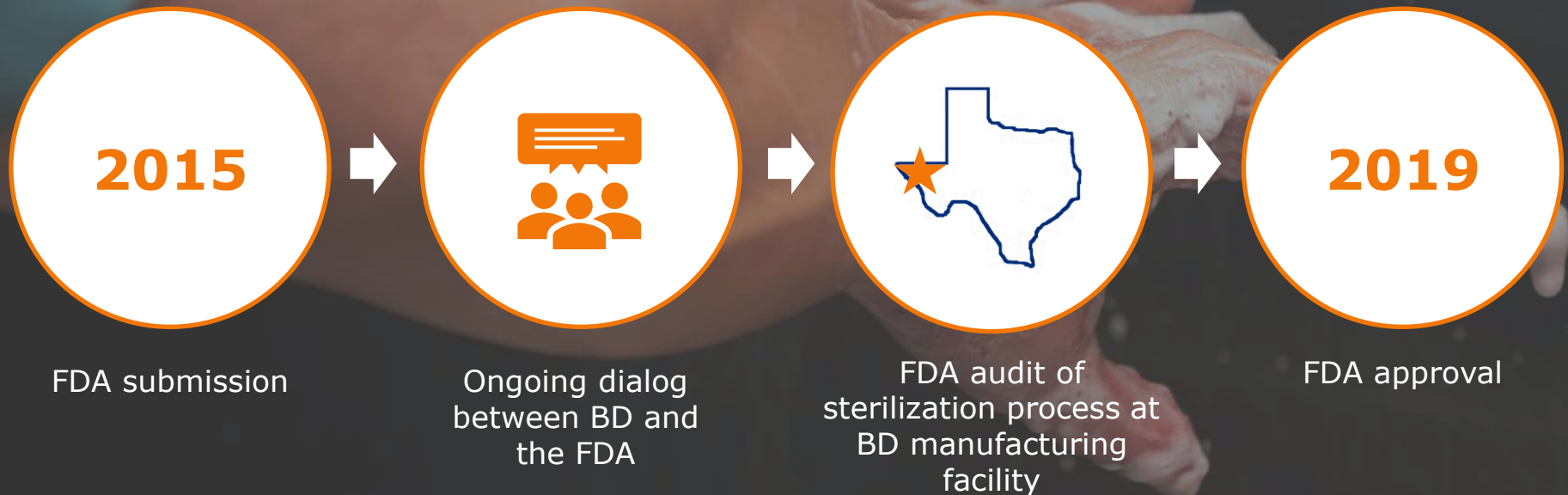


¹ Pyrek KM. *Infection Control Today*. 2013;July:1-30. <https://brnskill.com/wp-content/uploads/2013/12/FDA-investigates-Antiseptics-Sterility-and-potential-recommendations.pdf>. Accessed April 20, 2019. ² **Denton: See chapter pub**

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



¹ 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 solution¹

Less than a
1 in a million chance



chance that a viable microorganism can exist in a BD ChloraPrep™ applicator¹

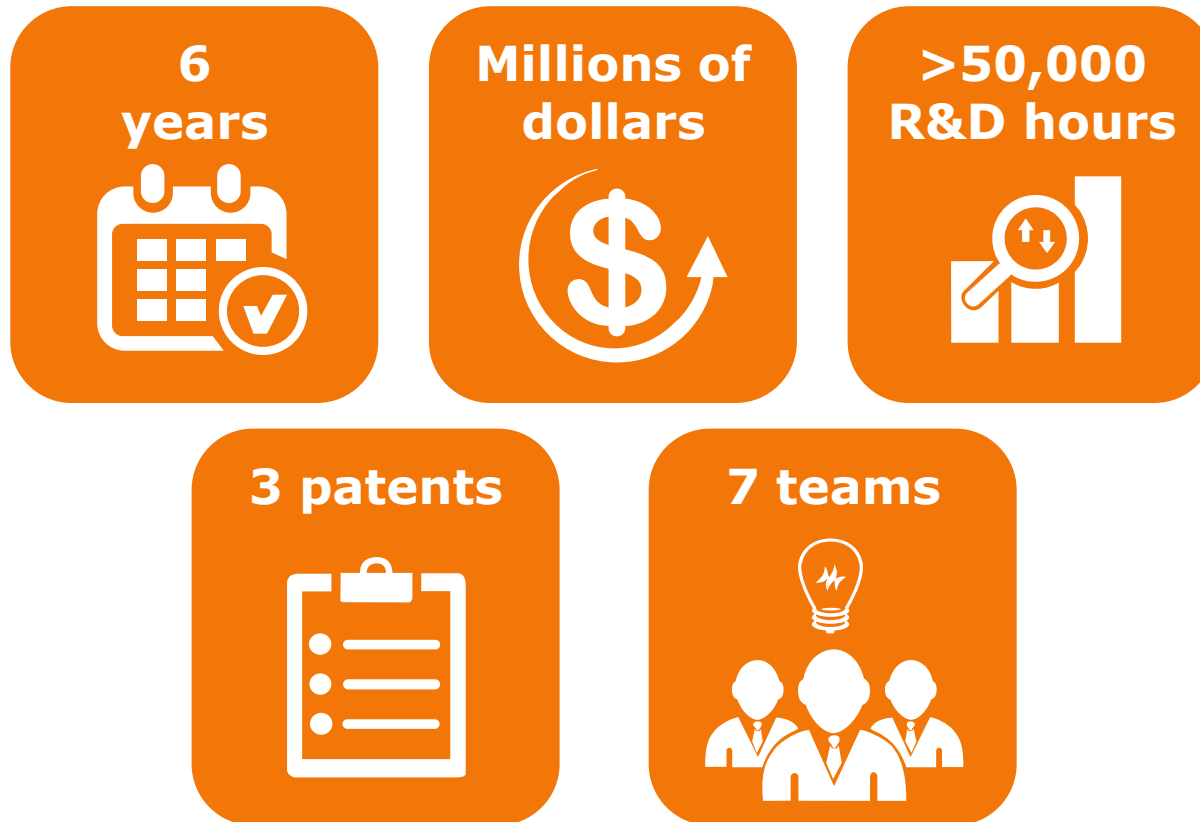
Sterility assurance level of 10⁻⁶



—the same level required for injectable products¹

¹ 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 ChloraPrep™ patient preoperative skin preparation include:

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



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
Broad spectrum¹⁻⁴	x	x	x	x	x	x
Fast acting¹⁻⁴	x			x	x	x
Persistent¹⁻⁴			x	x	x	x
Acting in the presence or organic matter¹⁻⁴			x		x	x
Minimizes the risk of intrinsic contamination						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.

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Providing peace of mind for clinicians and patients

BD ChloraPrep™ 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 ChloraPrep™ patient preoperative skin preparation with sterile solution, BD has achieved a new benchmark in skin antiseptis

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 launch**



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

To learn more, visit
bd.com/ChloraPrepSterileSolution

