



**BIOREP**<sup>®</sup>  
PRE-VALIDATED  
**SOLUTIONS**

# PRE-VALIDATED SOLUTIONS



Some of the biggest hurdles to getting a new medical device on the market are the time and expense that it takes to validate a cleaning protocol, design and validate a medical device packaging system, and validate a sterilization process.

## BIOREP TECHNOLOGIES PRE-VALIDATED SOLUTIONS & PLATFORMS:

Bclean®	Bsecure®	Bsterile®
↓	↓	↓
PRE-VALIDATED CLEANING	PRE-VALIDATED PACKAGING	PRE-VALIDATED STERILIZATION
TIME SAVINGS: ≈ 75% COST SAVINGS: ≈ 60%	TIME SAVINGS: ≈ 60% COST SAVINGS: ≈ 30%	TIME SAVINGS: ≈ 75% COST SAVINGS: ≈ 50%

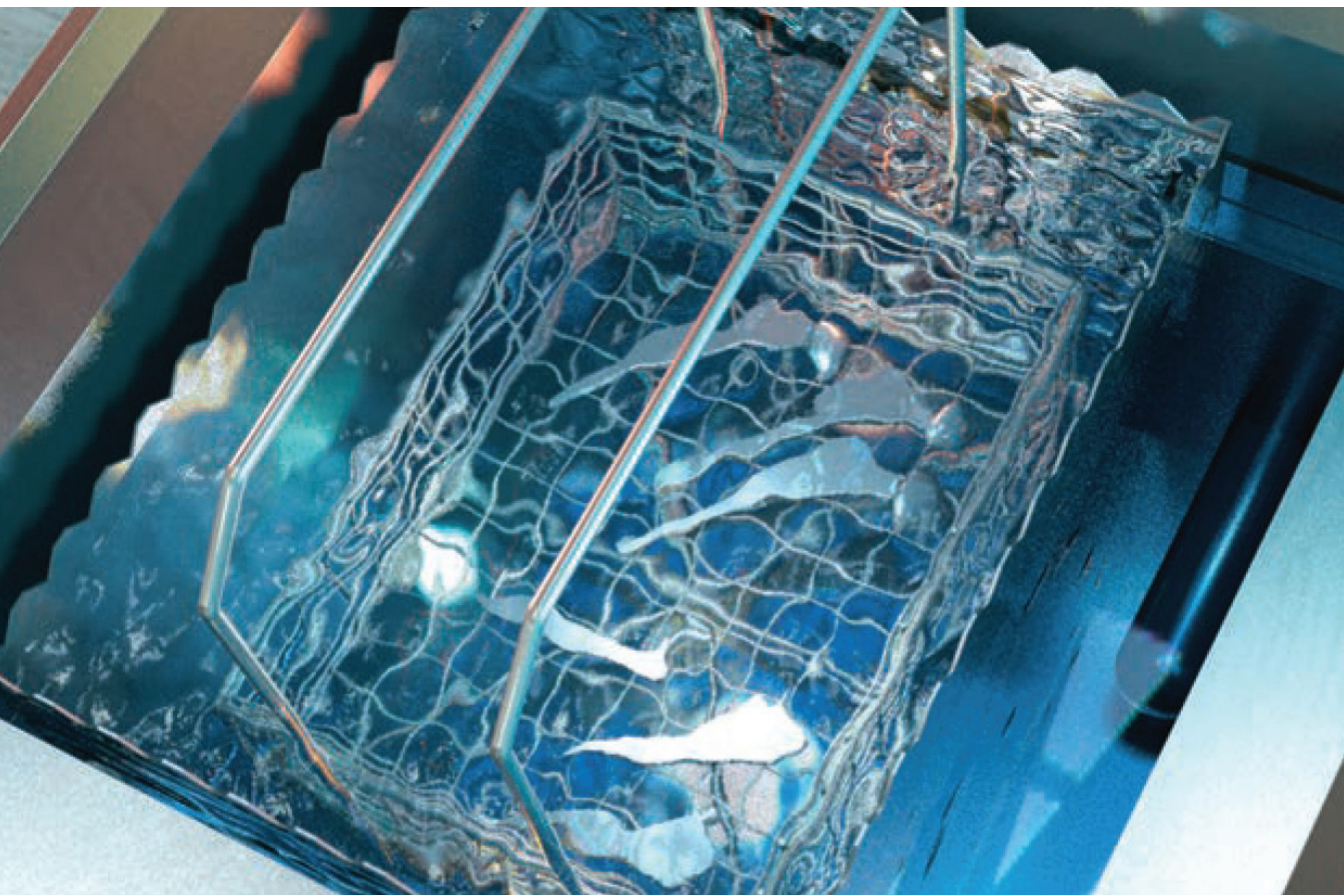
Our solutions save a valuable amount of time, money, and resources. This provides our customers a more efficient path to bring their products to market.



# Bclean<sup>®</sup>

**Bclean<sup>®</sup>** is a family of validated cleaning protocols that have been shown to be effective in removing manufacturing residues from CNC machined and injection molded components.

The protocols cover complex part geometries with the most common engineering resin families. Most medical device components will be typically covered under one of our Bclean<sup>®</sup> pre-validated protocols.



# Bsterile<sup>®</sup>

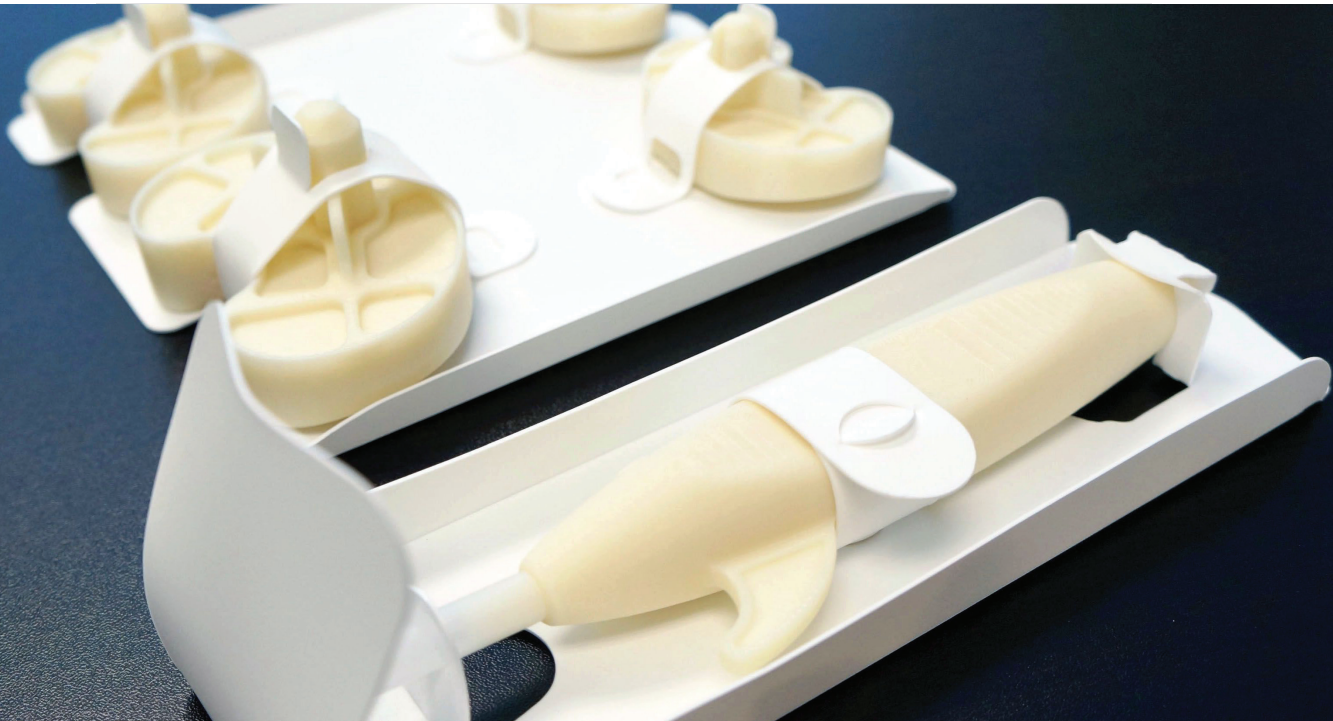
\*Under development

**Bsterile<sup>®</sup>** is a family of gamma and Ethylene Oxide (EtO) sterilization validations for different bioburden counts at different sterilization dosages and ranges.

Testing includes a determination of bioburden, bioburden recovery method validation, and bacteriostasis/fungistasis testing.



# Bsecure®



**Bsecure®** pouches can be customized to the needs of a specific component by adjusting the length and width of the pouch. This flexibility of customization offers a wide range of options for pre-validated packaging.

A seal validation has been completed with Poly-Tyvek® pouches for the Bsecure® offering, along with 3-year accelerated aging testing with Gamma sterilization and complete validation reports. Bsecure® offers flexible package options, including Tyvek® lid stock, standard label stock, IFU paper stock and SBS shelf boxes to provide a complete package system.

As a contract packaging alternative, **Bsecure®** reduces packaging development costs by over 30% and reduce development time by as much as 60% (depending on the actual device and customer specifications).

Bsecure® is a line of stock medical device packaging systems created in standard sizes for both tray- and pouch-based systems. Biorep® will have pre-validated stock Bsecure® trays, lids and pouches, which cover a range of sizes. Bsecure® trays could also be customized within the seal flange of the stock trays to accommodate a wide range of devices and retention features that ensure the contents are protected.





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Biorep is ISO 13485 certified and FDA registered. As a full-service development firm, Biorep has an exclusive focus on medical products and over 25 years of experience developing medical devices.