- 7. The Dr. Brown's[®] bottle system, nipples, non-metal bottle brush, AccuBrush[™] and one-piece silicone pacifiers may be sanitized using Dr. Brown's[®] Microwave Steam Sanitizing Bags.
- 8. Disassemble bottle system and place all cleaned parts including bottle/vessel, nipples, collar, internal vent system, non-metal brush, AccuBrush[™] and one-piece silicone pacifier in the bag. Place two ounces of water into the bag. Note: Do not place wire cleaning brush into the Dr. Brown's Microwave Steam Sanitizing Bag due to metal in the brush.
- Each Dr. Brown's Microwave Steam Sanitizing Bag may be used for a total of 20 cleaning cycles following the instructions for use on the bag. Be aware of the "Warning-Safety Note" to avoid injury to hands/face.

All Dr. Brown's^{*} bottle systems include durable plastic parts that can be cleaned along with all silicone pacifiers in the microwave steam sanitizing bags, top rack of dishwasher or steam sterilized (autoclaving^{*}). The Dr. Brown's^{*} Non-Metal Brush and AccuBrush^{**} can only be cleaned in the top rack of the dishwasher or microwave steam sanitizing bags. It cannot be steam sterilized.

Autoclave (Steam Sterilization) is recommended not to exceed 30 cycles and is NOT recommended for the Infant-Paced Feeding Valve (blue one-way valve), Non-Metal Bottle Brush, or AccuBrush^{}.

Dr. Brown's Medical

For more information about Dr. Brown's[•] Medical products:

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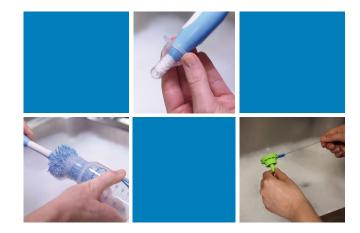




Cleaning Questions

and Answers





Q & As for Cleaning of Dr. Brown's[°] Medical products

- What are the manufacturer's guidelines for cleaning products before first use in a medical facility?
 Prior to first use, all bottle systems and nipples should be washed in hot soapy water and sanitized using a microwave steam sanitizing bag, electric sanitizer or microwave steam sanitizer.
- 2. Can Joint Commission influence the use of reusable bottle systems such as Dr. Brown's' Medical products? Hospital departments are required to develop and follow policy and procedures for cleaning reusable feeding products. Joint Commission will assure the policies and procedures as written are being implemented. It would be unusual for Joint Commission to deny the use unless the written policies are not being followed as designed.
- 3. Is it usual to experience an outbreak of thrush or infection after the implementation of Dr. Brown's Medical reusable products?

There have been no reports of continued thrush issues when the reusable products are cleaned according to the suggested cleaning guidelines AND the treatment for cases of thrush are treated according to approved policies and procedures.

- a. Dispose of all feeding items 24 hours after instituting an approved medicine for treatment including bottle systems, nipples, pacifiers, NG tubes, syringes, etc.
- **b.** Initiate good hand washing techniques. In the few cases reported, once the facility evaluated their procedures, flaws in the process were identified and addressed specifically not disposing NG tubes and/or inadequate hand washing techniques the eradication of thrush outbreaks was effective.

4. Each hospital must develop their own protocol that meets the requirements of their infection control department.

Below are a few individual hospital processes that have been shared with Dr. Brown's Medical. Please Note: these processes are not endorsed by Dr. Brown's Medical. (See Dr. Brown's Medical Suggested Cleaning Guidelines.) **a.** Hand wash with hot soapy water and air dry between each feed.

- **b.** Hand wash with hot soapy water, air dry between feeds and sanitize every 12 or 24 hours.
- c. Hand wash with hot soapy water, air dry between feeds and sanitize after each feed.
- **d.** Use a commercial dishwasher providing each patient their own dishwasher basket.
- e. Hand wash with soap and water after each feed and sterilize via steam sterilization (autoclave).
- f. Hand wash with soap and water after each use and dispose of after 24 hours of use to avoid the need to sanitize every 12 or 24 hours.
- g. Use Dr. Brown's° bottle systems as a disposable unit.

5. What if our water system is poor?

Most facilities have a process for a poor water system that includes cleaning bottles. It has been reported that some hospitals with poor water systems clean the bottles with sterile water.

6. Do the steam bags really sanitize the products? Yes. The below information addresses all inquiries regarding the effectiveness of the Dr. Brown's

microwaveable steam bags' ability to eradicate microorganisms when used according to the manufacturers recommendations. Testing was coordinated at an FDA registered; third-party accredited to ISO 17025 standards laboratory – Nelson Laboratories in Salt Lake City, Utah. The decontamination final report revealed >/= to 99.99% eradication of a highly moist-heat resistant microbe (Geobacillus stearothermophilus) when used per the guidelines on each bag.

- 7. What if a microwave is not permitted in our unit? Another form of cleaning the bottle systems should be adopted that is an acceptable department policy for cleaning reusable feeding products. While it is suggested to steam sanitize once every 24 hours, not all hospitals can comply with these recommendations and report effective sanitizing procedures.
- 8. Whose responsibility on the unit is it to clean bottles? Each facility must develop an effective and approved protocol that suits their requirements. Some hospitals assign the cleaning of Dr. Brown's^{*} bottles the responsibility of the parents and/or nursing and/or nursing assistants and some may require the families to take home daily and bring back after cleaned.
- 9. Do you have any sample cleaning protocols that you can share with us?

Yes, Dr. Brown's Medical can provide upon request through www.drbrownsmedical.com/contact

10. How do other hospitals make the transition to reusable products?

This transition takes planning with a variety of departments – therapy, nursing, nutrition, infection control, and education are a few. **It all starts with education of staff.** The Dr. Brown's Medical Team can assist with providing education on the benefits of the bottle, it's effectiveness for infant feedings and incorporating an approved cleaning. Developing a solid cleaning process is imperative for a successful transition and should be developed prior to initiation of use. Once the transition is complete, staff can evaluate the benefits of using Dr. Brown's^{*} products with all infants or some that meet a specific criterion. Products should be readily available to all staff who feed infants. 11. If we sanitize after each use, will the steam bags break down the nipple or parts quicker?

Sanitization of reusable feeding products such as the Dr. Brown's^{*} bottle systems and nipple once every 24 hours has been recommended by the American Dietary Association. Using the microwave steam bags after every use has not been tested by Handi-Craft Company, therefore information is unavailable on this specific use. It has been reported the green insert in the internal vent system can "shrink" and fits loosely on the reservoir causing the bottle system to leak at facilities where this is practiced. 24-hour sanitizing process with the microwave bags should be sufficient.

12. How many cycles of steam sterilization (autoclaving) can the bottle system and nipple sustain?

If following the autoclave method as recommended, each bottle system will be guaranteed for up to 30 cycles. Protocol was in line with all decontamination protocols including the U.S. guidelines for use with normal steam sterilization (autoclaving) process.

Steam Sterilization

- Repeat Exposure Testing Set Points Sterilizer Type Pre-Vacuum
- Preconditioning Pulses 3
- Temperature 132°C
- Full Cycle Exposure Time 04 minutes 00 seconds
- Dry Time 30 minutes 00 seconds
- Test Article Configuration Individually single pouch each test article and place on edge in sterilizer.

Cleaning and Sanitization

- 1. Wash cleaning surfaces with solution appropriate for areas with food contact.
- Prior to initial use, all Dr. Brown's^{*} products should be disassembled and thoroughly cleaned with a dishwashing detergent in water and sterilized/sanitized in a microwave steam bag/electric sterilizer/top-rack dishwasher or steam sterilization (autoclave^{*}). Dr. Brown's^{*} products should be washed with hot, soapy water and rinsed well between use.
- Use Dr. Brown's[®] Non-Metal Bottle Brush or AccuBrush[™] silicone bristles to eliminate debris from the interior of the Dr. Brown's[®] bottle/vessel and collar.
- Use the Wire Cleaning Brushes to thoroughly clean the internal vent system (i.e. insert and reservoir tube) and Infant-Paced Feeding Valve (blue one-way valve) only. Hospital use is recommended to replace the wire cleaning brush every 24 hours after use.
- **5.** Use the chevron tip at the bottom of either bottle brush to eliminate debris inside the tip of the nipple and assure the nipple hole is clean and open.
- Prior to each use and after cleaning, pull on the nipple in all directions before each use to make sure it does not tear. Replace the nipple prior to feeding if the integrity of the nipple is compromised.