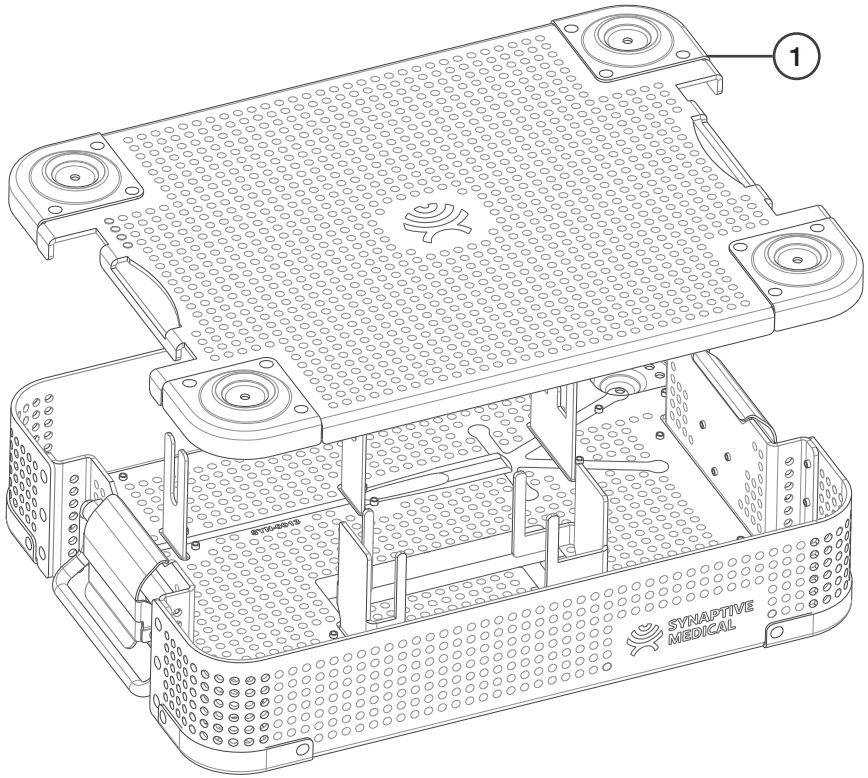
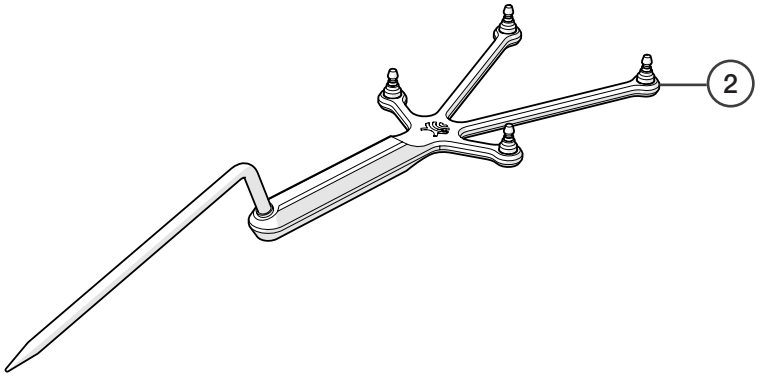
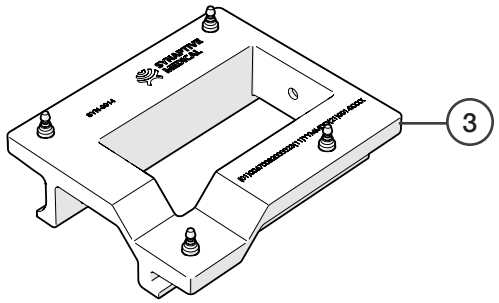
Synaptive

BrightMatter™ Pointer Cleaning and Sterilization Instructions







Item	Description	Part Number	Qty
1	Sterilizable Storage Tray	SYN-0596	1
2	Pointer	SYN-0642	1
3	Calibration Block	SYN-0014	1

These instructions for use are also available in electronic form at www.synaptivemedical.com/elFU. The electronic instructions for use may be viewed on any device that can access the internet and display PDF files. Access to the electronic instructions for use requires a password; to obtain the password, contact Synaptive Customer Service.

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⚠ **CAUTION: Risk of Damage to Equipment**

» Use only the sterilizable storage tray provided by Synaptive Medical to sterilize the Pointer and calibration block. Do not use the tray to sterilize any equipment other than the Pointer and calibration block.

» Do not stack anything on top of or underneath the sterilizable storage tray in the autoclave during sterilization.

NOTE: The use of cleaning, disinfection or sterilization methods or products not described in this manual may damage the Pointer.

Cleaning

The BrightMatter Pointer, calibration block, and sterilizable storage tray must be cleaned prior to sterilization:

1. If the passive reflective markers are still attached to the Pointer or calibration block, remove them and dispose of them properly.
2. Rinse the components under running tap water to remove visual soil.
3. Using a soft-bristled brush (M16), gently brush the entire surface of each component to remove any remaining debris.
4. Rinse the components in lukewarm running water.
5. Place the components in an automatic washer. The components must not contact any other item in the washer.
6. If you are using an enzymatic detergent such as Enzol® or Prolystica™, run the cycle listed in Table 1.

   If you are using an alkaline detergent such as neodisher® MediClean forte with a pH range 10.4-10.8 (2-10 ml/l, determined in deionized water, 20° C), run the cycle listed in Table 2.

   Use detergents at the manufacturer's recommended concentration and following the manufacturer's instructions.
7. When the washer cycle is complete, dry the components with a lint-free cloth.
8. Inspect the components for cleanliness, paying close attention to hard to reach areas.
9. Inspect the components for any signs of damage or any obvious physical defects (nicks, scratches, distortion in shape, etc.). If any component appears damaged, do not attempt to use it and contact Synaptive Customer Service for assistance.

Sterilization

To sterilize the BrightMatter Pointer and calibration block:

1. Place the clean Pointer and calibration block in the sterilizable storage tray provided by Synaptive Medical as indicated by the markings in the tray.
2. Double wrap the tray with 1-ply polypropylene wrap (e.g. Kimguard KC600).
3. Sterilize in an autoclave using the parameters described in Table 3.

Table 1 Recommended Automatic Washer Parameters for Enzymatic Detergents

Phase	Recirculation Time	Water	Temperature
Pre-wash 1	02:00 minutes	Tap water	Cold tap water
Enzyme wash	04:00 minutes	Tap water	Hot tap water
Rinse 1	02:00 minutes	Reverse osmosis or distilled water	109.4° F (43° C)
Drying	06:00 minutes	N/A	210° F (98.8° C)

Table 2 Recommended Automatic Washer Parameters for Alkaline Detergents

Phase	Recirculation Time	Water	Temperature
Pre-wash 1	02:00 minutes	Tap water	Cold tap water
Wash 1	04:00 minutes	Tap water	109.4° F (43° C)
Rinse 1	02:00 minutes	Reverse osmosis or distilled water	109.4° F (43° C)
Drying	06:00 minutes	N/A	210° F (98.8° C)

Table 3 Recommended Autoclave Parameters

Sterilization Type	Prevacuum	
Method	Moist heat sterilization according to EN ISO 17665	
Preconditioning Pulses	4	
Temperature	270° F (132° C)	273.2° F (134° C)
Exposure Time *	4 minutes	3 minutes
Minimum Dry Time	30 minutes	30 minutes

* It is acceptable to extend the exposure time if necessary to comply with established protocols at your site. However, because prolonged exposure time may affect product life, carefully inspect tools for damage before use. Prolonged exposure times may also affect the minimum dry time. Always verify that the product is free of moisture after sterilization.

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