

Pointer Set Components

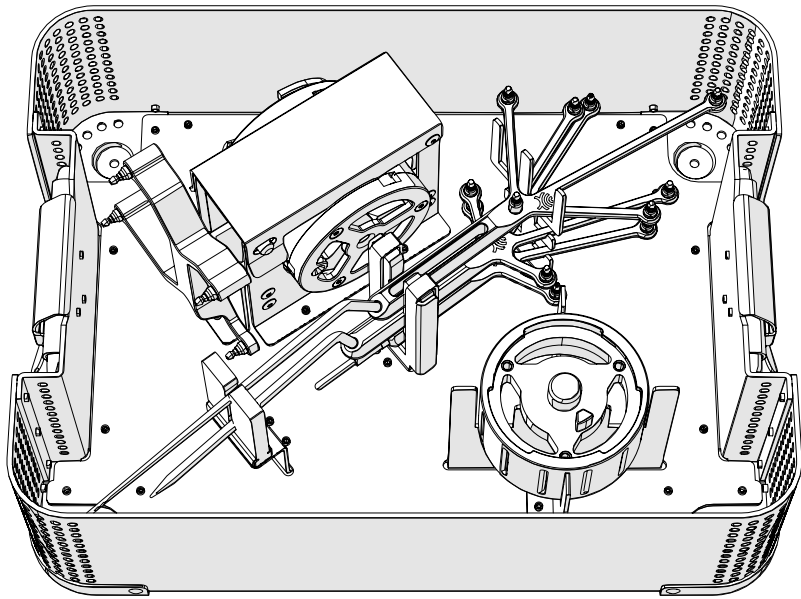
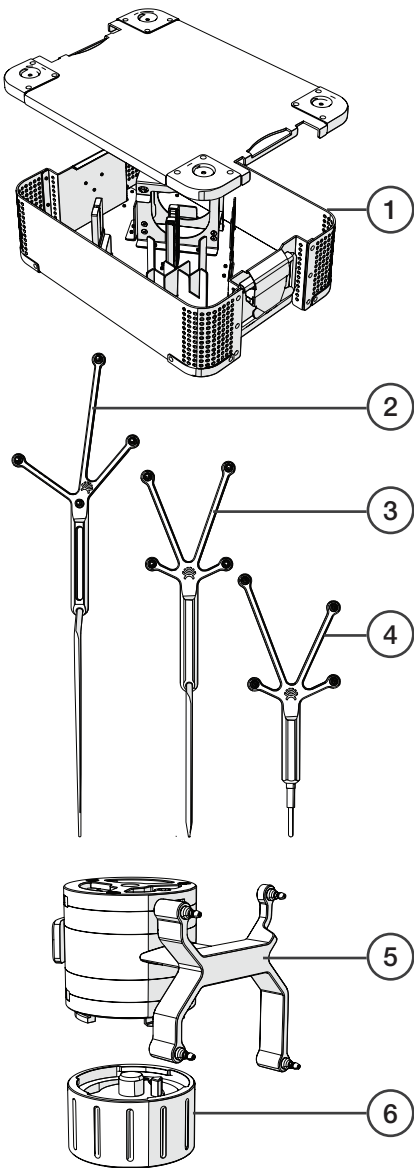


Figure 1 Placement of components in tray

Item	Description	Part Number	Qty
1	Sterilizable storage tray	SYN-0754	1
2	Long Pointer	SYN-0975	1
3	Standard Pointer	SYN-0642	1
4	Short Pointer *	SYN-0559	1
5	Multi-Tool Calibration Device body	SYN-0755	1
6	Multi-Tool Calibration Device removable base	SYN-0784	1

* Your Pointer set may not include Short Pointer

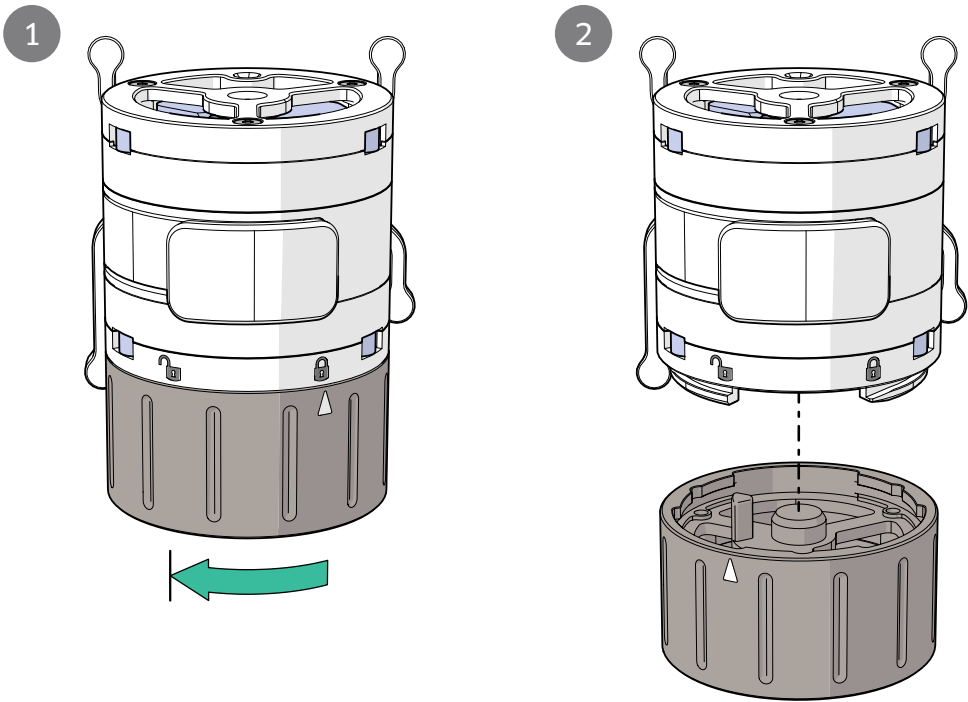
Calibration Device Disassembly

⚠ WARNING: Risk of Patient Injury

Never assemble or disassemble tools over the surgical site.

⚠ CAUTION: Risk of Damage to Equipment

The reflective tracking spheres are single-use only and must be properly disposed of after each procedure. Do not attempt to sterilize the tracking spheres in an autoclave. Doing so will destroy the tracking spheres and may damage other tools in the autoclave tray.



- ⚠ CAUTION: Risk of Operator Injury
- » Wear all necessary personal protective equipment when handling contaminated components and cleaning supplies.
- ⚠ CAUTION: Risk of Damage to Equipment
- » Use only the sterilizable storage tray provided by Synaptive Medical to clean and sterilize the Synaptive Pointer set components. Do not use the tray to clean or sterilize any equipment other than the Synaptive Pointer set components.
- » Do not stack anything on top of or underneath the sterilizable storage tray in the automatic washer during cleaning or in the autoclave during sterilization.

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

Cleaning

- The Synaptive Pointer set components must be cleaned prior to sterilization.
1. Inspect the sterilizable storage tray. If the tray does not meet the following criteria, do not use it and contact Synaptive customer service for assistance.

» Brackets must not be broken or deformed

» Latches must close securely

» There must be no evidence of corrosion
2. If the reflective tracking spheres are still attached to the tools, remove them and dispose of them properly.
3. Disassemble the Multi-Tool Calibration Device (see instructions, over).
4. Rinse the components under running tap water to remove visual soil. While rinsing:

a. Use a soft-bristled brush (M16) to gently brush the entire surface of each tool to remove any remaining debris.

b. Use a soft-bristled lumen brush to brush the lumen in the Multi-Tool Calibration Device.
5. Rinse the components in lukewarm running water. Place each component in the brackets assigned to it in the sterilizable storage tray provided with the Synaptive Pointer set.

- NOTE: The Pointers must be placed in their brackets in the tray in the following order (from bottom to top): Short Pointer, Standard Pointer, Long Pointer.
- The Multi-Tool Calibration Device body must be placed in the bracket in the orientation shown in Figure 1 (see over) and the latch securing it in place must be properly fastened.
6. Place the tray in an automatic washer.

» If you are using an enzymatic detergent such as Enzol® or Prolystica™, run the cycle listed in Table 1 below.

» 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 below.

Follow the manufacturer’s recommendations regarding detergent use and concentration.

Use a motor speed setting of high.

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	Tap water	109.4° F (43° C)
Rinse 2	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	Tap water	109.4° F (43° C)
Rinse 2	02:00 minutes	Reverse osmosis or distilled water	109.4° F (43° C)
Drying	06:00 minutes	N/A	210° F (98.8° C)

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 all components for any signs of damage or any obvious physical defects (nicks, scratches, cracks in the weld seams). If any component appears damaged, do not attempt to use it and contact Synaptive customer service for assistance.

Sterilization

- To sterilize the Synaptive Pointer set components:
1. Place each component in the brackets assigned to it in the sterilizable storage tray provided with the Synaptive Pointer set as shown in Figure 1 (see over).

2. Double wrap the tray with a 1-ply polypropylene wrap with appropriate regulatory clearance in your jurisdiction (e.g. Kimguard KC600).

3. Sterilize in an autoclave using the parameters described in Table 3 below.

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 lifespan, 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.
4. Remove the tray from the autoclave and allow it to cool for at least 15 minutes.

Shelf Life

The shelf life of sterilized components depends on the sterile barrier maintained by the polypropylene barrier and the storage and handling conditions. Your site is responsible for defining and enforcing a maximum shelf life for sterilized instruments.