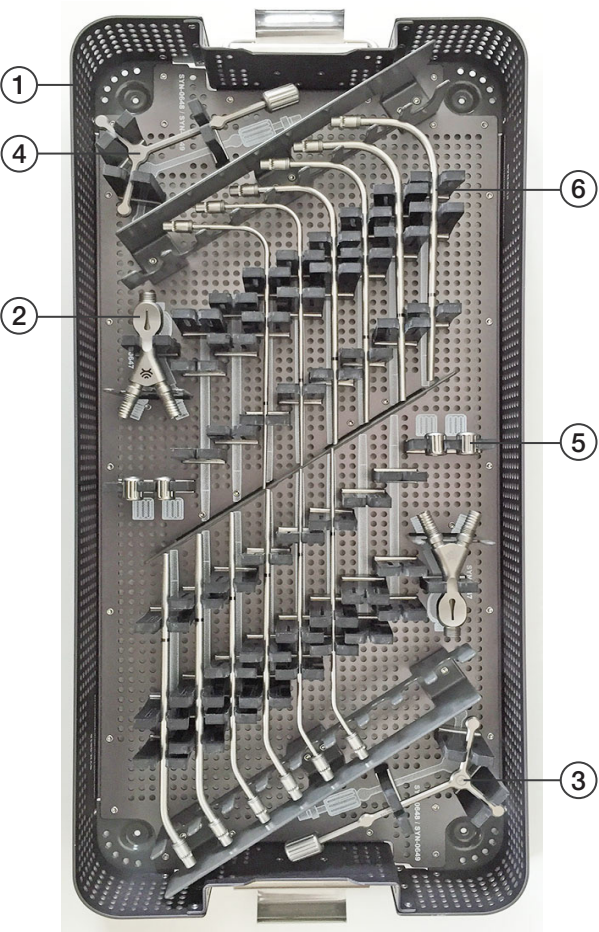


Trackable Suction Tool Components



| Item | Description                 | Part Number | Quantity |
|------|-----------------------------|-------------|----------|
| 1    | Sterilizable Storage Tray   | SYN-0618    | 1        |
| 2    | Handle                      | SYN-0647    | 2        |
| 3    | Tracking Array 1            | SYN-0648    | 1        |
| 4    | Tracking Array 2            | SYN-0649    | 1        |
| 5    | Tube Nut                    | SYN-0874    | 4        |
| 6    | Suction Tubes:              |             |          |
|      | 160 mm 6 FR 30° Bend Angle  | SYN-0651    | 2*       |
|      | 160 mm 10 FR 30° Bend Angle | SYN-0652    | 2*       |
|      | 160 mm 12 FR 30° Bend Angle | SYN-0653    | 2*       |
|      | 160 mm 6 FR 90° Bend Angle  | SYN-0654    | 2*       |
|      | 160 mm 10 FR 90° Bend Angle | SYN-0655    | 2*       |
|      | 160 mm 12 FR 90° Bend Angle | SYN-0656    | 2*       |
|      | 80 mm 4 FR 30° Bend Angle   | SYN-0671    | 2*       |
|      | 80 mm 6 FR 30° Bend Angle   | SYN-0672    | 2*       |
|      | 80 mm 8 FR 30° Bend Angle   | SYN-0673    | 2*       |
|      | 80 mm 10 FR 30° Bend Angle  | SYN-0674    | 2*       |
|      | 120 mm 4 FR 30° Bend Angle  | SYN-0675    | 2*       |
|      | 120 mm 6 FR 30° Bend Angle  | SYN-0676    | 2*       |
|      | 120 mm 8 FR 30° Bend Angle  | SYN-0677    | 2*       |
|      | 120 mm 10 FR 30° Bend Angle | SYN-0678    | 2*       |

\* Quantity in a standard set. Your set may include more or fewer of these components.

Trackable Suction Tool Disassembly

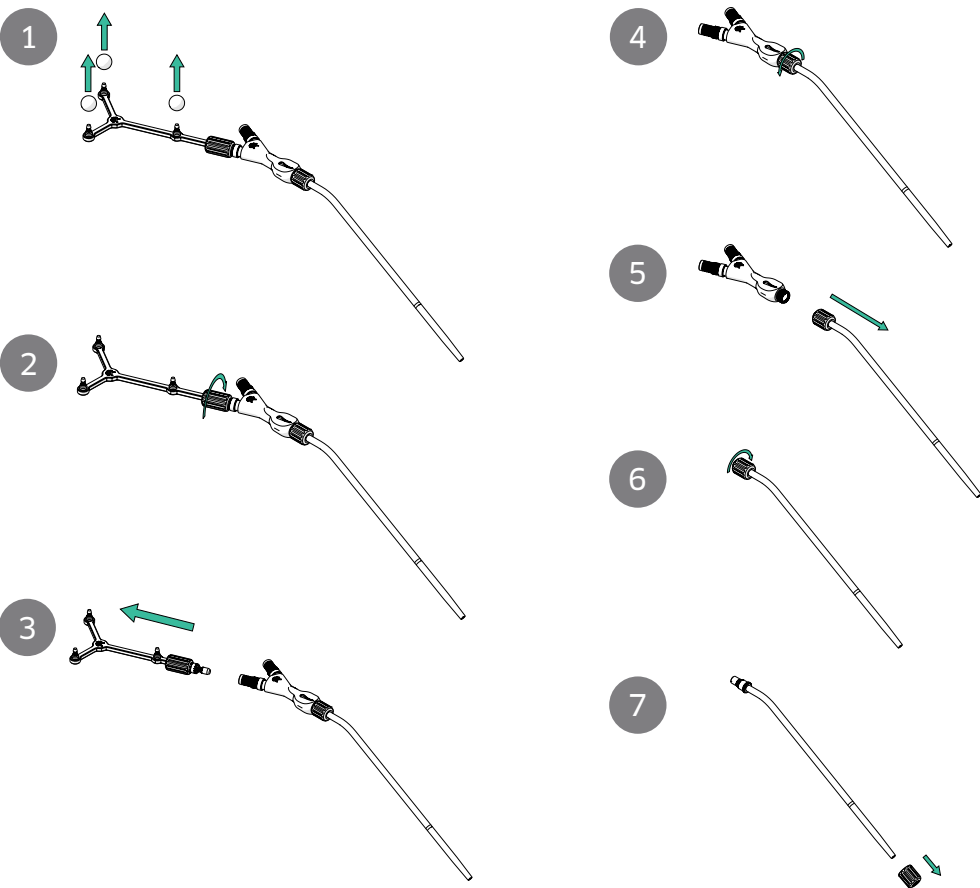
⚠ WARNING: Risk of Patient Injury

Never assemble and disassemble the Trackable Suction tools over the surgical site.

⚠ CAUTION: Risk of Damage to Equipment

Do not apply excessive force when assembling or disassembling the Trackable Suction tools, especially in areas where threads are used for fastening.

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



- ⚠ **WARNING: Risk of Operator Injury**
- » Wear all necessary personal protective equipment when handling contaminated components and cleaning supplies.
- ⚠ **WARNING: Risk of Infection**
- » Failure to follow these cleaning and sterilization instructions may result in the Trackable Suction tool being inadequately cleaned or sterilized.
- » Suction tubes that are damaged, flattened, or that have been bent at an angle greater than 90° cannot be sterilized. Discard these suction tubes.
- ⚠ **CAUTION: Risk of Damage to Equipment**
- » Use only the sterilizable storage tray provided by Synaptive Medical to clean and sterilize the Trackable Suction tool components. Do not use the tray to clean or sterilize any equipment other than the Trackable Suction tool 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 Trackable Suction tool components.**

Cleaning

- The Trackable Suction tool components must be cleaned prior to sterilization:
1. If the Trackable Suction tools are assembled, disassemble them (see instructions, over).

2. Rinse the components under running tap water to remove visual soil. While rinsing:

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

b. Use a soft-bristled lumen brush to brush the lumens. Insert the lumen brush through both ends of the lumen and move it back and forth through both ends of the lumen to loosen soil. If the lumen brush does not fit into the lumen, use a small gauged wire and move it back and forth through both ends of the lumen.

3. Rinse the components in lukewarm running water. Use a 60 mL syringe to flush out the lumens.

4. Place each component in the brackets assigned to it in the sterilizable storage tray provided with the Trackable Suction tools.

» Place the tracking arrays in the tray with the posts facing down.
- » The brackets designated for the tubes are generic to all tubes. Any tube may be placed in any pair of brackets.

» Two suction tubes can be stacked in each pair of brackets provided that the tube on the bottom has a smaller diameter than the tube above it. The brackets have notches inside to indicate where the tubes should sit.
- 
5. 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. 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.

Follow the manufacturer’s recommendations regarding detergent use and concentration. Use a motor speedsetting of high.
- Table 1 Recommended 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 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) |
6. When the washer cycle is complete, dry the components with a lint-free cloth.

7. Inspect the components for cleanliness, paying close attention to hard-to-reach areas.

8. Inspect the components for any signs of damage such as: nicks, scratches, thread debris, kinks in the suction tubes, cracks in weld seams, corrosion, tracking sphere posts damaged or not perpendicular to tracking array. If any component appears damaged, do not attempt to use it and contact Synaptive Customer Service for assistance.
- Sterilization
- To sterilize the Trackable Suction tool components:
1. Place each tool component in the brackets assigned to it in the sterilizable storage tray provided with Trackable Suction. For more information, see the notes in step 4 of the cleaning instructions.

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

3. Sterilize in an autoclave using the parameters described in Table 3.
- 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 a 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.
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CE2797

EU Authorized Representative  
MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany

CHREP

Swiss Authorized Representative  
MDSS CH GmbH  
Laurenzenvorstadt 61  
5000 Aarau, Switzerland

Sponsored in Australia by:  
Inovanz Pty Ltd  
10/ 24 Lakeside Drive, Burwood East  
Victoria, 3151

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