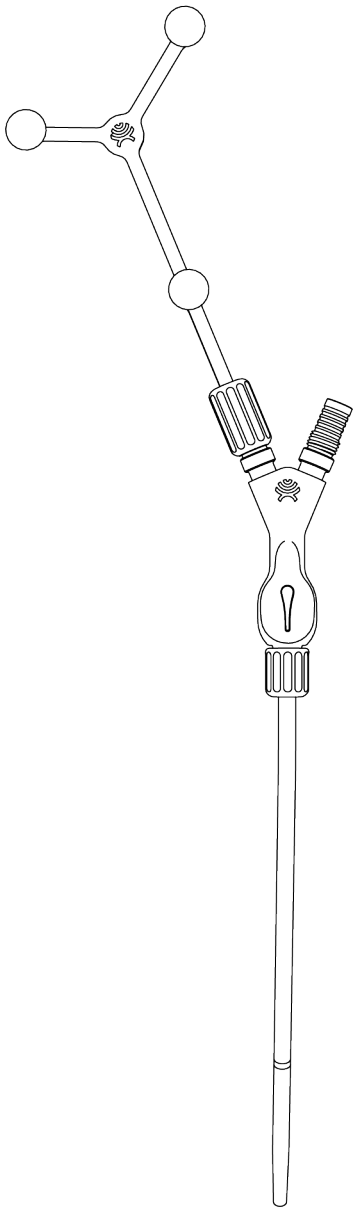
Trackable Suction

User Manual

MAN-0579 Revision K



Synaptive

User Manual

Synaptive™ Trackable Suction

SYN-0657, SYN-0783

Synaptive

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These instructions for use are also available in electronic form at www.synaptivemedical.com/eIFU. 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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1.0 Product and Safety Symbols

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Symbol	Title	Reference	Description
	Caution	ISO 7000-0434A	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	ISO 7000-3082	Indicates the medical device manufacturer. The date of manufacture, as well as the name and address of the manufacturer, can be combined in this symbol.
	Consult instructions for use or consult electronic instructions for use	ISO 7000-1641	Indicates the need for the user to consult the instructions for use.
	Non-sterile	ISO 7000-2609	Indicates a medical device that has not been subjected to a sterilization process.
	Catalog number	ISO 7000-2493	To identify the manufacturer's catalog number, for example on a medical device or the corresponding packaging.
	Serial number	ISO 7000-2498	To identify the manufacturer's serial number, for example on a medical device or its packaging.
	Keep dry	ISO 7000-0626	Indicates a medical device that needs to be protected from moisture.

Table 2 ISO 7010 - Graphical symbols - Safety colors and safety signs - Registered safety signs

Symbol	Title	Reference	Description
	General warning sign	ISO 7010-W001	To signify a general warning.

Table 3 Product Safety Certification Marks

Symbol	Title	Reference	Description
CE	CE mark	N/A	Conformity with the essential requirements set out in the European Directives.
EC REP	Authorized representative in the European Community/ European Union	N/A	Indicates the authorized representative in the European Community/European Union.
CH REP	Authorised representative for Switzerland	N/A	Indicates the authorised representative in Switzerland.

Table 4 Other Symbols

Symbol	Description
Rx only	U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare provider.
MD	Indicates the item is a medical device.

2.0 Intended Use

Synaptive™ Trackable Suction is a vacuum-powered body fluid suction apparatus that is used to remove fluids and small solid masses from the surgical site through aspiration. It is powered by an external source of vacuum. The device can be used to provide surgical suction for procedures while optionally allowing a localization system to track its position in 3D space. The tracked position of the suction tool may be then used to focus a surgical camera at the tip of the suction tool.

Typical users of the device are medical professionals such as surgeons and other Operating Room staff.

2.1 Intended Use Environment

Trackable Suction is intended for use in hospitals, clinics, and other medical institutions.

3.0 Warnings and Precautions

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a surgeon.

WARNING: Risk of Patient Injury

Applying excessive suction to tissue may result in patient injury. Always use the suction control slot on the Trackable Suction tool handle to carefully regulate the amount of suction applied to the tissue.

Applying excessive force to tissue may result in patient injury.

Dropping the tool, or tool components, may result in patient injury. Hold the tool securely and do not assemble or disassemble the tool over the surgical site. When assembling the tool, tighten nuts and attach tracking spheres firmly to ensure tool components do not fall and injure the patient.

Collisions between the suction tube and tools with moving parts (for example drills and cutting tools) may create metal debris, potentially harming the patient.

Using a damaged tool may impact the safety and performance of the device. Always inspect the tool and suction tubes before use and do not use a damaged tool.

The Trackable Suction tool has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of the Trackable Suction tool in the MR environment is unknown.

WARNING: Risk of Patient or Operator Injury

Bend the malleable suction tubes only as described in this manual. Applying excessive force when bending a malleable suction tube may collapse the tube creating sharp edges.

WARNING: Risk of Infection

The Trackable Suction tool is not sterile when delivered. The use of non-sterile instruments poses a risk of infection to patients, users, and third parties. Clean and sterilize the tool before initial use and before and after every subsequent use using the cleaning and sterilization procedures described in the sterilization instruction sheet accompanying the tool.

Failure to follow prescribed 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.

The materials used in the Trackable Suction tool have been tested and certified for up to 24 hours of exposure to the patient.

WARNING: Risk of Procedure Delay Due to Loss of Tool Function

An obstruction in the suction tube may impair the performance of this device. If a suction tube becomes obstructed, it can be cleared using conventional methods.

Attach the suction hose firmly. This device may not perform as intended if the suction hose is not properly connected.

WARNING: Risk of Procedure Delay Due to Loss of Tool Function

Use only the suction hose size recommended in this manual. Using a non-recommended suction hose size may impact the performance of this device.

The suction tube nuts are small and can easily be misplaced. To avoid misplacing the nuts, store them in the sterilizable storage tray and take them out only when needed. The suction tube nuts are not considered part of the tube and will not be replaced with replacement tubes. If a suction tube becomes damaged, be sure to remove and store the nut before disposing of the tube.

Follow the instructions in this manual to attach tracking spheres to the tracking array properly. If tracking spheres are not firmly attached to the tracking array posts, the tracking camera may not be able to track the tool.

Only suction tubes marked with the "malleable" pictogram may be bent. Applying excessive force to a non-malleable suction tube may damage the tube and render it unusable.

Bend the malleable suction tubes only as described in this manual. Bending the malleable tubes outside of the designated bendable area may result in the system being unable to calibrate the tool. Unbending and re-bending a tube at the same location may damage the tube.

Although the malleable suction tubes have been designed to be easily bent, in some cases it might be difficult to achieve the desired bend.

4.0 Synaptive Customer Service Information

For 24-hour access to clinical and technical support, contact Synaptive customer service.

Phone:	1-844-462-7246 (North America)
	1-647-925-3435 (International)
Email:	service@synaptivemedical.com

5.0 About Trackable Suction

Trackable Suction is a surgical suction tool that can be tracked and localized using other Synaptive products.

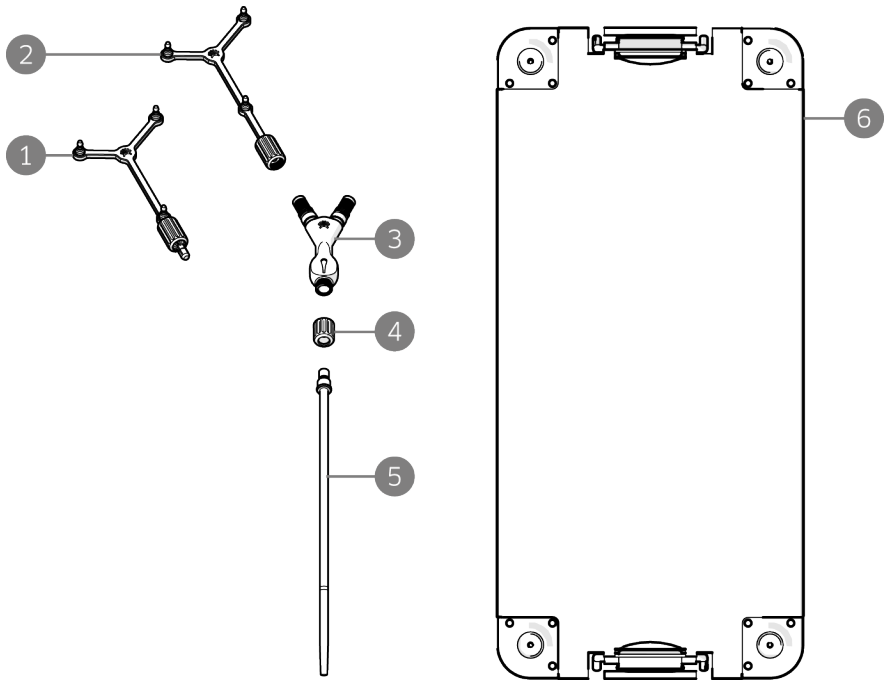


Figure 1 Trackable Suction components

1	Tracking array 1	**4**	Tube nut
2	Tracking array 2	**5**	Suction tube (see below for a list of all suction tube configurations)
3	Handle	**6**	Sterilizable storage tray (not to scale)

5.1 Suction Tubes

Suction tubes are distinguished by their diameter, bend angle, working length, and malleability.

Table 5 Suction Tube Configurations

French Size	Bend Angle	Working Length		
		80 mm	120 mm	160 mm
4	30	Malleable	Malleable	-
6	30	Malleable	Malleable	Non-malleable
6	90	-	-	Non-malleable
8	30	Malleable	Malleable	-
10	30	Malleable	Malleable	Non-malleable
10	90	-	-	Non-malleable
12	30	-	-	Non-malleable
12	90	-	-	Non-malleable

The standard suction tool sets include two of each of either the malleable or non-malleable tubes listed in Table 5. Additional tubes may be ordered from Synaptive Medical. For more information, see 11.0 Consumables and Replaceable Parts on page 16.

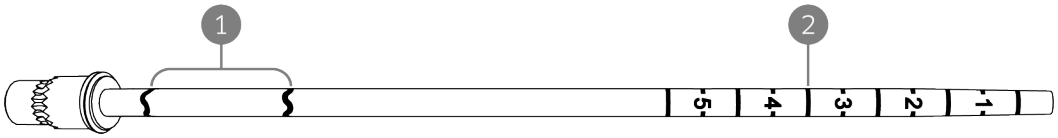


Figure 2 Suction tube markings

1 Pictograms indicating that this suction tube is malleable and the malleable area
2 Suction tubes are marked with depth indicators at 5 mm intervals

All suction tubes are made of stainless steel and are tapered to reduce the risk of clogging.

NOTE: Suction tubes are prone to damage because they are used in close proximity to drilling and cutting tools. The rate at which the suction tubes become damaged depends on how frequently they are used and the types of procedures they are used in. Always inspect a suction tube carefully before using it. If a suction tube appears damaged or becomes kinked, do not use it and order a replacement.

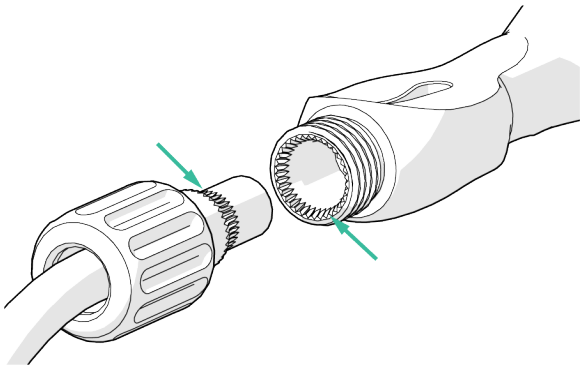


Figure 3 Detail view showing external splines on the tube and internal splines in the handle

Splines on the tubes and inside the handles allow the tubes to be attached to a handle in one of 18 rotational positions to maximize flexibility for the procedure.

Suction tubes are connected to the handle by a nut. Four nuts are included in the Trackable Suction standard set.

NOTE: The suction tube nuts are small and can easily be misplaced. To avoid misplacing the nuts, store them in the sterilizable storage tray and take them out only when needed. If a suction tube becomes damaged, be sure to remove and store the nut before disposing of the tube.

5.2 Handle

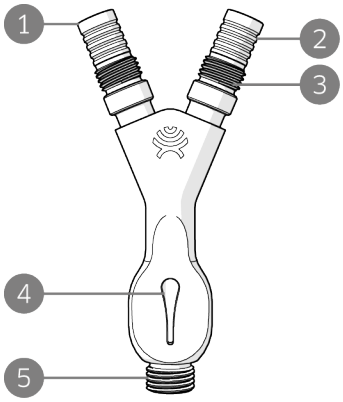


Figure 4 Trackable Suction handle

The Trackable Suction standard set includes two handles, allowing you to use two suction tools simultaneously or interchangeably during a procedure. The handles are made of titanium and have a teardrop-shaped suction control slot for precisely regulating the amount of suction.

1 Suction hose/tracking array fitting (2)
2 Ribbing for securing hose
3 Threads for connecting a tracking array
4 Suction control slot
5 Threads for connecting suction tube

The suction hose can be attached to the handle using either of the two fittings. Hoses with a smaller diameter will fit over the ribbing on the fitting up to the threading for the reference tree nut. Larger diameter hoses will fit over the threading. The recommended suction hose size for use with Trackable Suction is 1/4" ID.

5.3 Tracking Arrays

The Trackable Suction tracking arrays hold the tracking spheres used by the optical tracking system to track the location of the tool in space.

NOTE: The Trackable Suction standard set does not include tracking spheres. Tracking spheres can be ordered from Synaptive Medical. For more information, see 11.0 Consumables and Replaceable Parts on page 16.

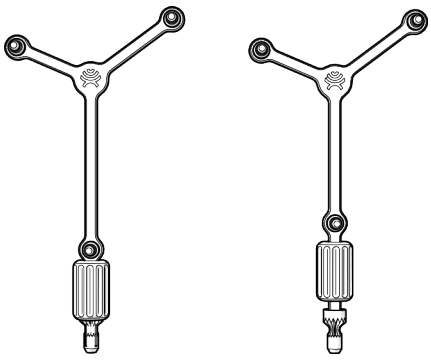


Figure 5 Tracking arrays

Two unique tracking arrays are provided with the Trackable Suction standard set so that you can track two suction tools at the same time.

The tracking arrays are made of titanium and are connected to the handle by a nut. Like the suction tubes, the tracking arrays have splines that allow the tracking array to be attached to the handle in one of 16 rotational positions to maximize flexibility for the procedure.

5.4 Sterilizable Storage Tray

A sterilizable storage tray is provided for sterilizing and storing the suction tool components. The tray holds:

- 2 handles
- 2 tracking arrays
- 4 nuts
- Up to 32 suction tubes (double stacked)

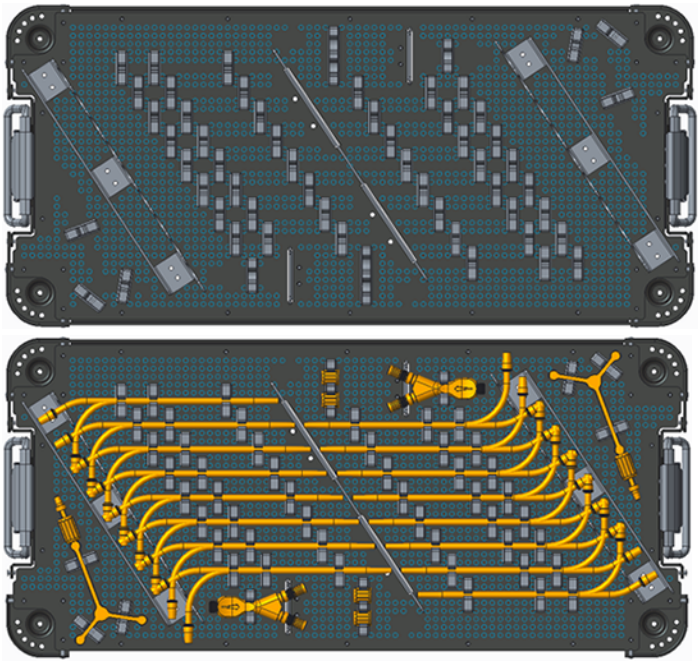


Figure 6 Trackable Suction sterilizable storage tray, empty (top) and with Suction components (bottom)

Note that the tracking arrays should be placed in the tray such that the posts face down.

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.

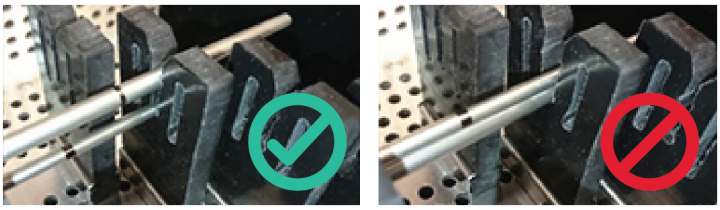


Figure 7 Two suction tubes correctly stacked (left) and incorrectly stacked (right)

For information about sterilizing the Trackable Suction components, see 10.0 Sterilization on page 14.

6.0 Assembly

NOTE: Make sure that the suction tube and tracking array are fully seated in the handle before tightening the nut. Tighten nuts firmly to ensure the suction tool components stay connected during use.

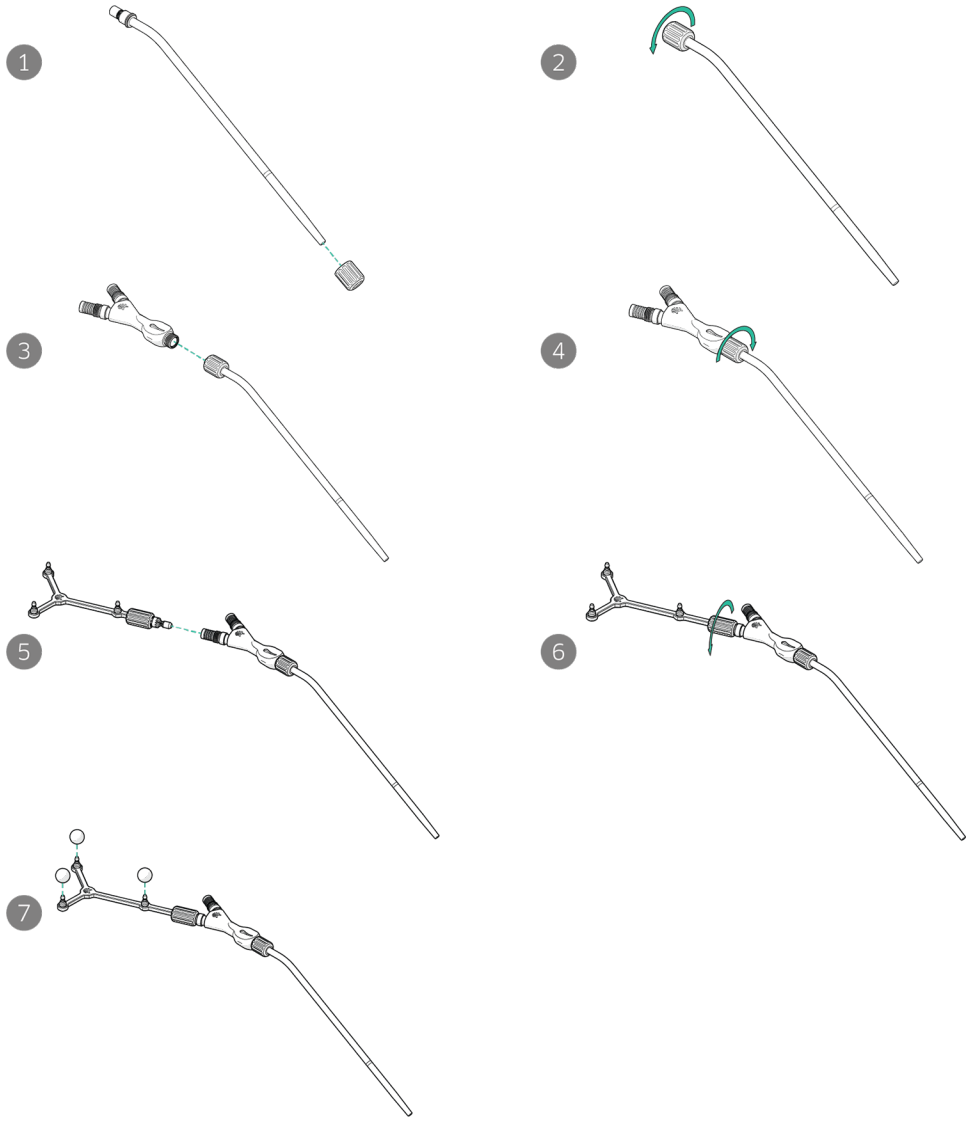


Figure 8 Trackable Suction assembly steps. Reverse these steps to disassemble.

NOTE: The tracking array may be attached to either fitting on the top of the handle.

7.0 Working with Reflective Tracking Spheres

Synaptive trackable tools are tracked using spherical passive reflective markers. In order to track a tool, all the spheres on the tool must be:

- Properly attached

  To attach the tracking spheres to a tool, push them firmly onto the posts on the tool until they stop. You should feel the spheres snap into place. If a sphere is loose, or is not pushed as far as it will go onto the post, the tracking camera may not be able to track the tool.

- Visible to the tracking camera

  To prevent the loss of tool tracking, avoid obstructing the tracking camera's view of the spheres when using a trackable tool.

- Clean

  If the tracking spheres become soiled during use they can be replaced, but be aware of the following points:

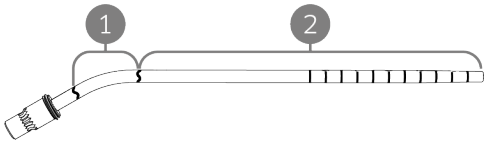
  - Do not attempt to replace tracking spheres over the surgical site
  - If you replace a tracking sphere on a calibrated tool, you must re-calibrate the tool before using it again

Perform a visual inspection before using tracking spheres. Do not use the spheres if they, or their packaging, appear damaged.

The tracking spheres are single-use only and must be properly disposed of after each use.

8.0 Working with Malleable Suction Tubes

Suction tubes that bear the "malleable" pictograms ( ) may be bent anywhere between the two pictograms.



1 Bend tube anywhere in this area

2 **Do not bend in this area**

Figure 9 Malleable suction tube features

To bend a suction tube, place your thumbs at the location where you want the bend to be and apply force on the ends of the suction tube.

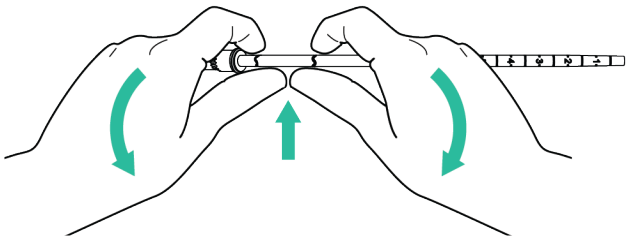


Figure 10 Bending a malleable suction tube

NOTE: Unbending and re-bending a tube at the same location may damage the tube. Do not bend suction tubes more than 90°.

NOTE: In order to maintain accurate localization, you must re-localize the suction tool in Modus V any time you change the bend in a malleable suction tube.

9.0 Using the Trackable Suction Tools

Keep the following points in mind when using the Trackable Suction tools:

- Before each use, always inspect the tool for damage such as:
  - Nicks
  - Scratches
  - Thread debris
  - Kinks in the suction tube
  - Cracks in weld seams
  - Corrosion
  - Tracking sphere posts damaged or not perpendicular to the tracking array

  Also, inspect tools if you suspect that they have become damaged during use. Do not use a tool that appears to be damaged. If you suspect that a suction tube has become damaged during use, discontinue using it.
- Before using the suction tool, verify that the suction hose is firmly connected to the handle.
- Always disconnect the suction hose before making an adjustment to the tool.
- To prevent the possibility of components falling on the patient, always assemble and disassemble the tool away from the surgical site.
- If a suction tube becomes obstructed, it can be cleared using conventional methods.

10.0 Sterilization

The Trackable Suction components must be sterilized in an autoclave. For cleaning and sterilization instructions, see the Trackable Suction sterilization information sheet (Synaptive part number MAN-0580).

The 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.

NOTE: Immediately following a procedure, rinse the sterilizable components as needed to remove visible contaminants and debris. Do not let contaminants dry before cleaning.

11.0 Consumables and Replaceable Parts

To order consumables or replacement parts, contact sales@synaptivemedical.com.

Table 6 Trackable Suction Consumables

Part			Part Number
Tracking spheres (1 box of 48 [12 trays of 4 in box])			SYN-0533
Malleable Suction Tubes (1 pack of 3 tubes)			
Working Length	Bend Angle	French Size	Part Number
80 mm	30°	4	SYN-0759
		6	SYN-0761
		8	SYN-0763
		10	SYN-0765
120 mm	30°	4	SYN-0760
		6	SYN-0762
		8	SYN-0764
		10	SYN-0766
Non-malleable Suction Tubes (1 pack of 3 tubes)			
Working Length	Bend Angle	French Size	Part Number
160 mm	30°	6	SYN-0663
		10	SYN-0664
		12	SYN-0665
	90°	6	SYN-0666
		10	SYN-0667
		12	SYN-0668

Table 7 Trackable Suction Replaceable Parts

Part	Part Number
Suction Handle	SYN-0647
Tracking Array 1	SYN-0648
Tracking Array 2	SYN-0649
Tube Nut	SYN-0874
Sterilizable Storage Tray	SYN-0618

12.0 Device Lifetime

Trackable Suction has an expected lifespan of seven years.

The Trackable Suction tubes are semi-disposable and end of life is determined by wear, damage and corrosion experienced during use. Always inspect Suction components prior to use and replace if worn or damaged.

13.0 Disposal

Dispose of tracking spheres as pathological waste.

Before disposing of any Synaptive product, contact Synaptive customer service or your supplier for further information.

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