

CONVENTUS CAGE™ – PH
Procedure Instruments
Instrument Tray
Cleaning and Sterilization



CONVENTUS
ORTHOPAEDICS

1. WARNINGS AND PRECAUTIONS

- 1.1. Caution should be exercised when handling instruments with sharp points, or cutting/drilling edges. Anytime instruments are to be cleaned (either contaminated or potentially contaminated) Personal Protective Equipment should be used.
- 1.2. Instruments should remain moistened prior to cleaning, do not allow instruments to dry.
- 1.3. Do not use metal brushes or scouring pads during manual cleaning process.
- 1.4. Use cleaning agents with low foaming surfactants for manual cleaning to enable visualization of the instruments in the cleaning solution. The cleaning agents selected must be easily rinsed from the instrument.
- 1.5. Enzymatic-neutral pH cleaning solutions are recommended for cleaning reusable instruments.
- 1.6. Some of the Conventus instruments are aluminum with an anodized surface. These instruments must not come into contact with strong acidic or alkaline cleaners and disinfectants, or solutions that contain iodine or chlorine.
- 1.7. For exposed features (e.g., site preparation instrument blades), saturate the crevices with copious amounts of cleaning solution to flush out any soil. Scrub the surface with a soft bristled brush to remove all visible soil from the surface and crevices. Rotate the instruments while scrubbing to ensure all surfaces and crevices are clean.
- 1.8. Mineral oil or silicone lubricants should not be used on instruments.

2. INSTRUMENT PREPARATION

Instrument trays/lids and index boxes must be cleaned separately from instruments. Non-sterile, single use implants (e.g., plates, screws, and washers) may remain in their respective caddy for reprocessing. Screw caddy lids should be closed and secure during automated cleaning.

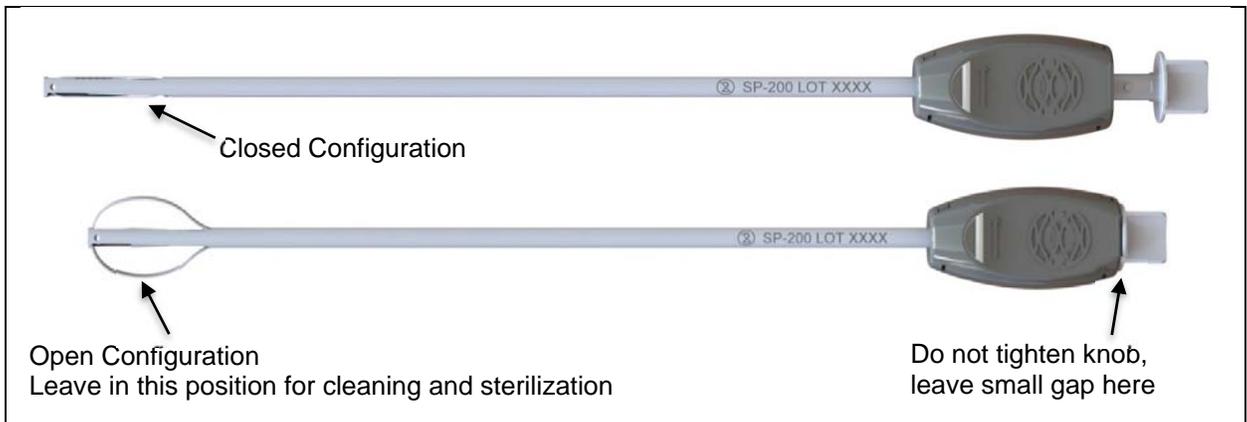
Remove major contaminants in the operating room before returning the instruments to the tray. It is preferable to remove contaminants using a dry method. If contaminants are removed using a wet method, place the instruments in a prepared solution directly after they are used. The instruments must be disassembled and open as much as possible. The entire product (including grooves, holes, lumens, etc.) must be sufficiently flushed and covered with solution.

3. INSTRUMENT CLEANING

Remove each instrument from the Instrument Set. Disconnect any mating parts (e.g., drill/driver bits). Remove any pins or wires that may be inside cannulated instruments. Do not remove or tighten any screws or knobs. Instruments with specific instructions beyond the general cleaning is noted in the illustrations below. Clean each instrument after each use according to the following instructions:

1. Rinse each instrument under running water for two (2) minutes to remove visible soil. Scrub each instrument, including any cannulation, with an appropriately sized soft-bristled brush while rinsing. If applicable, actuate any moving parts (e.g., threads, knobs or pivot points) and scrub with a soft-bristled brush while rinsing.
2. For cannulated instruments, flush the internal lumens by connecting a pressurized water line to an open port until water flows freely out the opposite end. Once water flows freely, flush for an additional two (2) minutes.
3. Prepare a fresh enzymatic-neutral pH detergent (such as Enzol® Enzymatic Detergent) solution per the detergent manufacturer's recommendations and place the solution in an ultrasonic cleaner.
4. Immerse the instrument in the detergent solution and sonicate for twenty (20) minutes. Where applicable, leave instruments in an open configuration.
5. Scrub instrument, including any cannulation, with a soft-bristled brush to remove any remaining debris if necessary. If applicable, actuate any moving parts (e.g., threads, knobs or pivot points) and scrub with a soft-bristled brush while rinsing.
6. Rinse the instrument again with distilled or reverse osmosis water for two (2) minutes. If applicable, actuate any moving parts (e.g., threads, knobs or pivot points) and flush all surfaces during rinse.

7. For cannulated instruments, flush the internal lumens again with distilled or reverse osmosis water by connecting a pressurized water line to an open port until water flows freely out the opposite end. Once water flows freely, flush for an additional two (2) minutes.
8. Dry the instrument with a clean, soft lint free cloth or clean compressed air.
9. Automated washing may be used after manual washing is complete.
10. Examine the instrument under normal lighting for visible soil. If present, repeat cleaning.
11. Visually inspect under normal lighting for corrosion, damage, and function. Discard if corroded, damaged, or does not function as intended.
12. Movable parts, such as threads and hinges, should be lubricated prior to sterilization with a non-silicone based surgical instrument lubricant as needed to ensure smooth operation. Unique instructions are provide in the illustrations below.



Site Preparation Instrument Shown in “Open” and “Closed” Configuration



Delivery Handle

4. **AUTOMATED CLEANING/DISINFECTION INSTRUCTIONS**

Automated washing systems are not recommended as the only cleaning method for these surgical instruments. As previously described, an automated cleaning system may be used after manual cleaning is complete. All surgical instruments and trays should be thoroughly inspected prior to sterilization to ensure the cleaning was effective.

5. **STERILIZATION INSTRUCTIONS**

The tray and instruments should be inspected to ensure they were thoroughly cleaned prior to sterilization. If any soil is present, they should be re-cleaned.

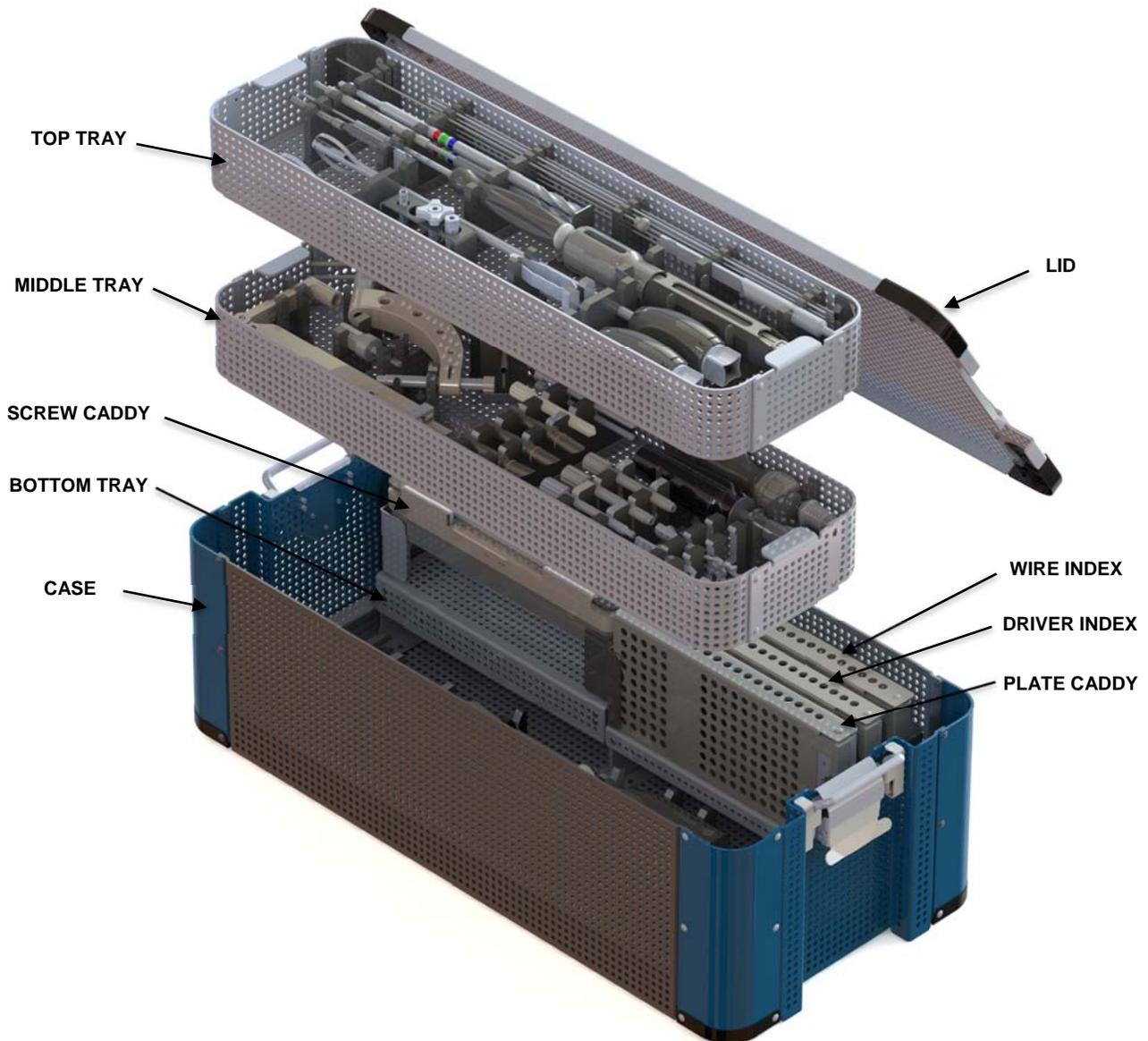
As the manufacturer, Conventus recommends sterilizing in the provided instrument tray wrapped in standard FDA cleared medical grade steam sterilization wrap or within an Aesculap® rigid sterilization container, Model (JK446). Do not stack trays during sterilization. The following sterilization parameters have been validated by Conventus.

Cycle	Minimum Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum Autoclave	132°C	4 Minutes	30 Minutes
Pre-vacuum Autoclave	135°C	3 Minutes	30 Minutes

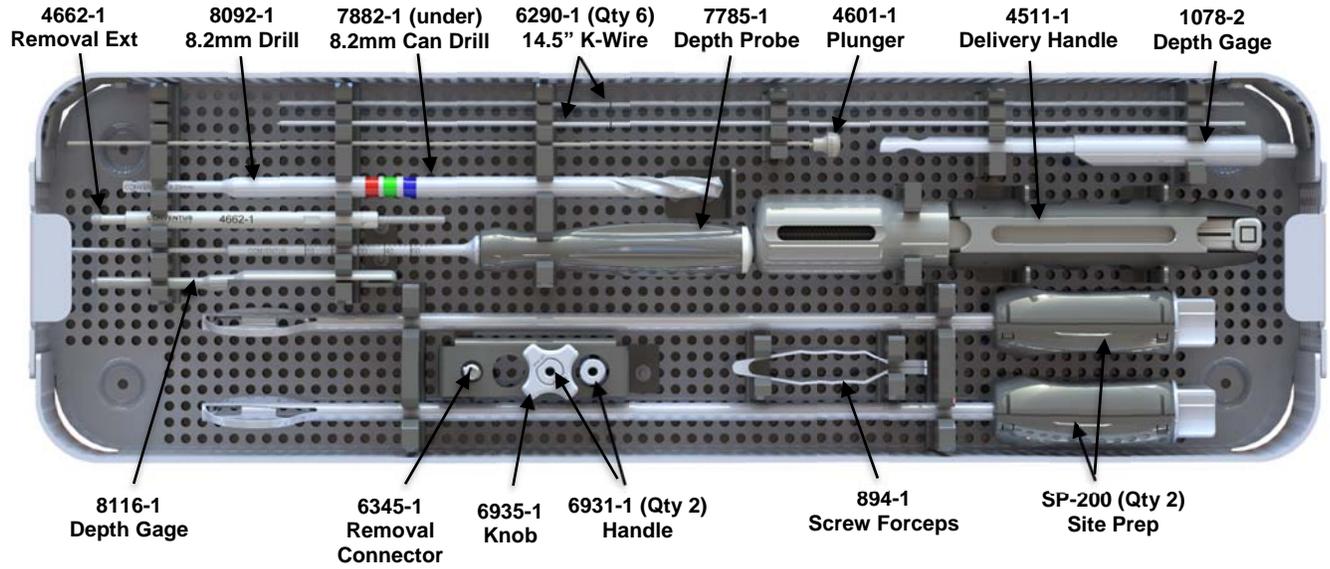
Other configurations and sterilization parameters may also be suitable, but the user must validate any deviation from these instructions provided by Conventus.

6. INSTRUMENT SET LAYOUT

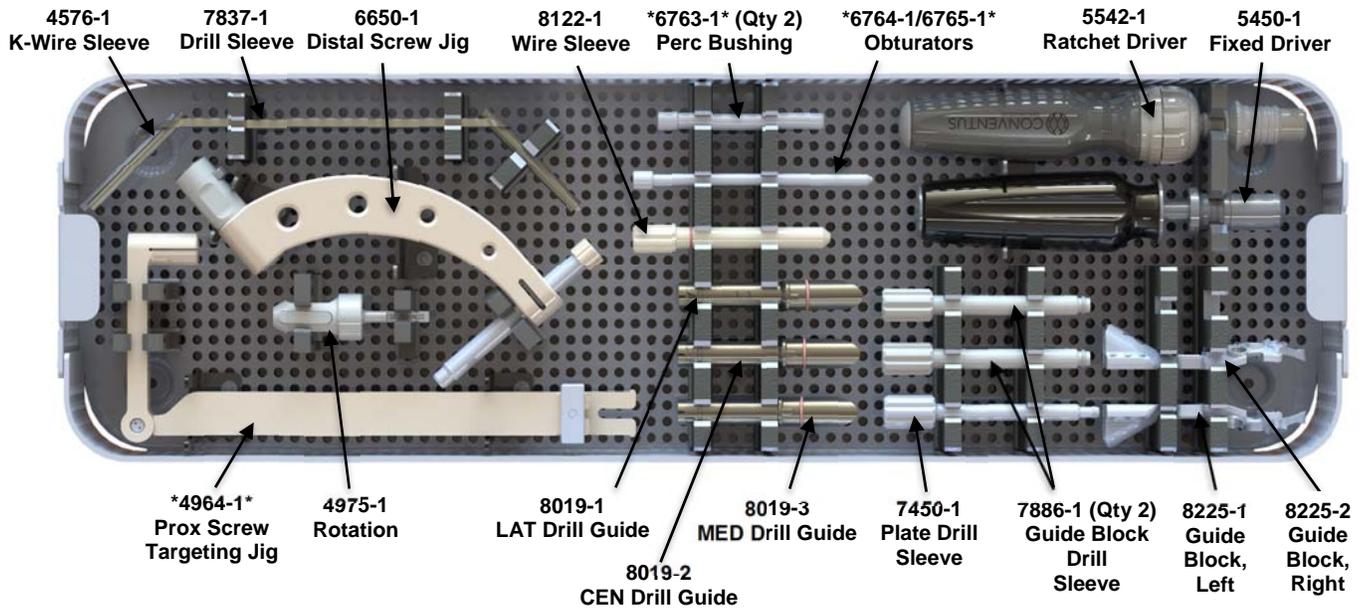
The main set consists of multiple tray levels, driver index, wire index, plate caddy, and screw caddy. Each bracket is designed to hold a specific instrument denoted by the item's model number in the illustration below. Items indicated with asterisks are available in select sets only. For items that do not have a dedicated bracket, place on the pin mat in the bottom tray. Place instruments in set according to the following layouts:



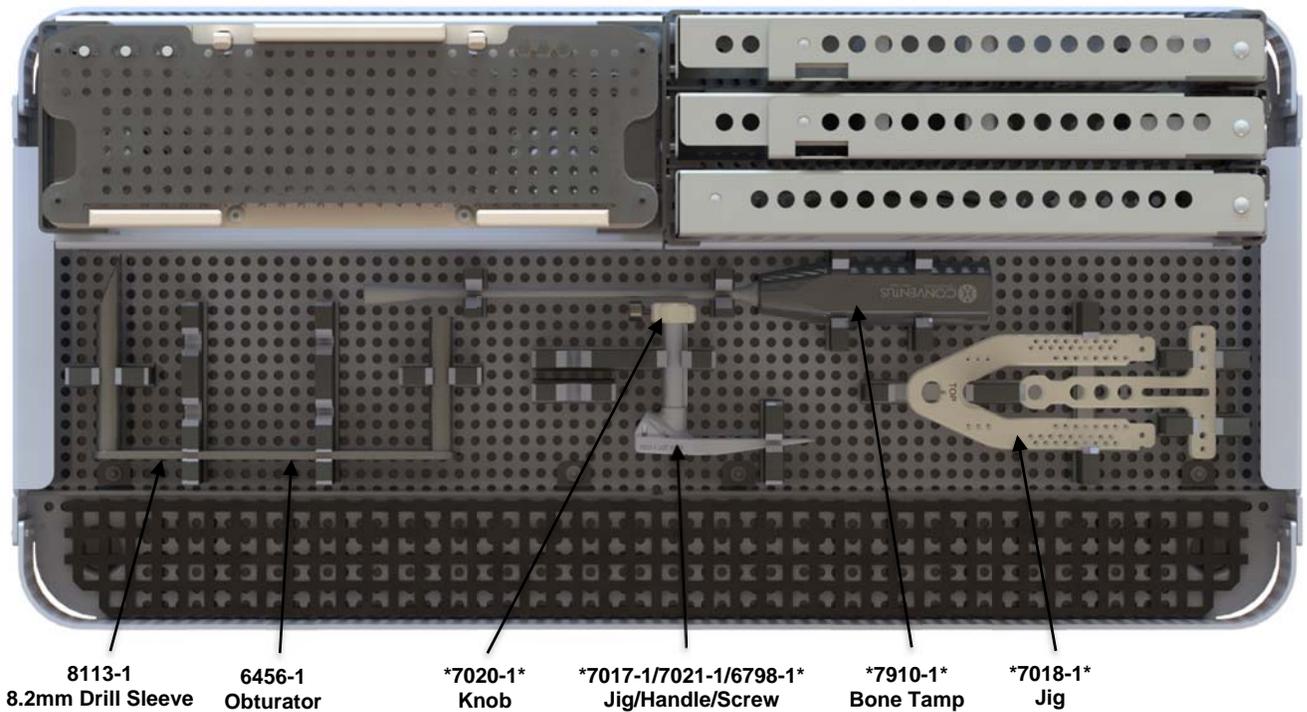
TOP TRAY



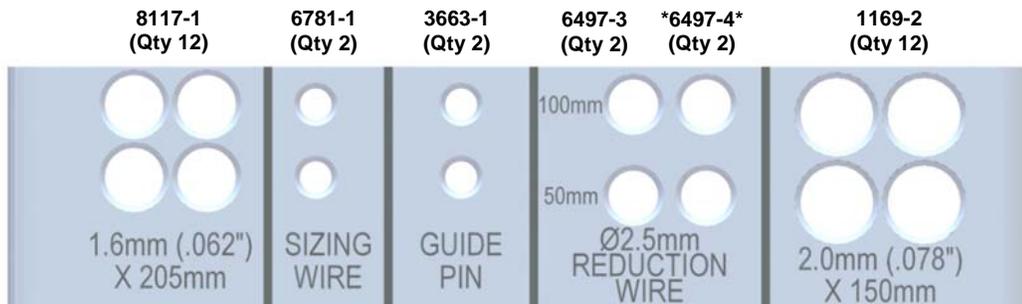
MIDDLE TRAY



BOTTOM TRAY



WIRE INDEX



DRIVER INDEX

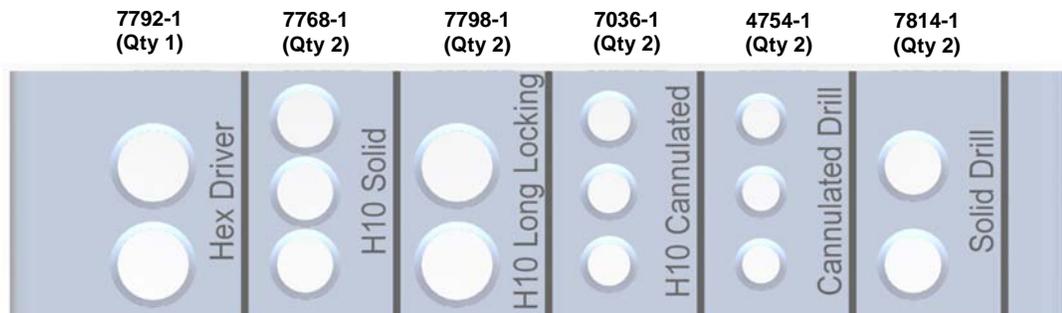
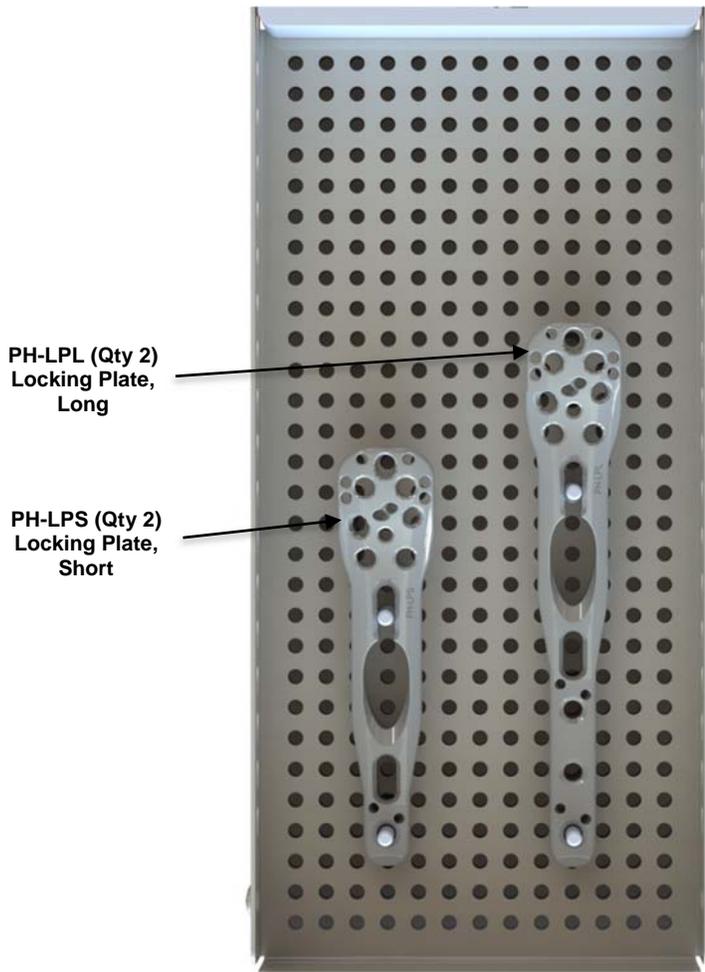


PLATE CADDY

SCREW CADDY





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