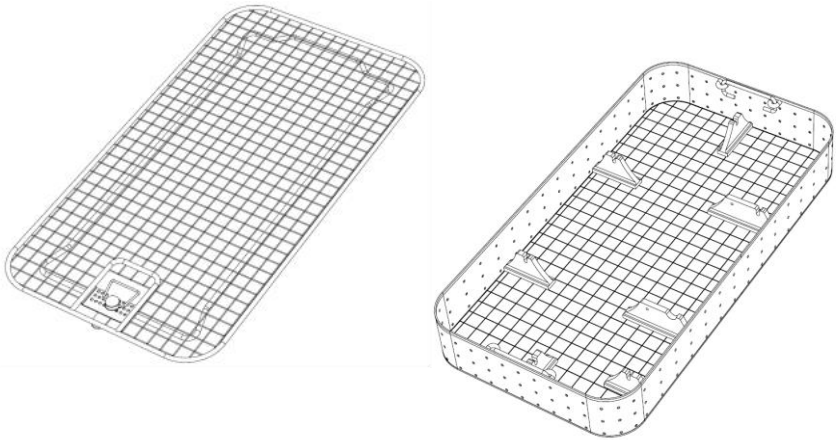


Sterilisation Tray A-T02 Instructions for use



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INDICATIONS FOR USE

The Khelix Sterilisation Tray is intended to secure and protect the reusable Khelix Electrophysiology Catheter Handle/Guidewire before procedure and after procedure during transportation between Electrophysiology laboratory and Central Sterilisation Departments (CSD), as well as during automated cleaning and steam sterilisation.

DEVICE DESCRIPTION

The stainless-steel tray perforated body and lid have multiple holes to facilitate access of steam during steam autoclave. Brackets allow securement of reusable Khelix catheter handles/guidewire within the tray body*. The tray is originally supplied non-sterile.

Top View without Lid

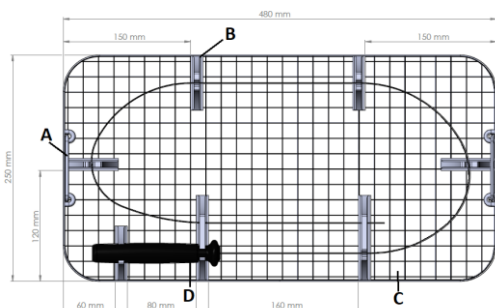


Figure 1: Sterilisation tray A-T02 top view securing reusable electrophysiology catheter handle/guidewire

A. Tray Handle	B. Support bracket
C. Tray holes	D. Reusable EP Catheter Handle/Guidewire*

*Reusable Electrophysiology Catheters are supplied separately available for purchase at CathRx Ltd.

* AT02 Sterilisation Tray can also be ordered directly from supplier Van Straten Medical under order code: 262601639. Central telephone number: +31 30 602 38 30 Website: www.vanstratenmedical.com

INTENDED USER

Khelix Sterilisation tray is intended to be used by the hospital's central sterilisation department to secure and hold medical device during reprocessing.

CLEANING of TRAY

Manual cleaning

1. Use ENZOL® Enzymatic Detergent solution (or equivalent)
2. Remove all visible soil and contaminants using a soft bristle brush. Submerge entire tray body and lid separately while cleaning to aid in the removal of contaminants and to reduce splashing of detergent on personnel for a minimum of 2 minutes. See rinsing instruction on the detergent label.
3. Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent.
4. After drying, inspect visually for evidence of soil remaining on tray.

Automated cleaning

Automated cleaning for tray alone or with reusable handle within the tray. Separate the tray body and lid while washing to maximize exposure.

The following wash parameters were validated in Steris Reliance Vision Washer using Ecolab Neutral Enzymatic Detergent (or equivalent):

1. Pre-Wash for 2 minutes 30 seconds with unheated tap water.
2. Wash Cycle:
 - Stage 1: Wash for 1 minute 30 seconds at 122F (50 °C)
 - Stage 2: Wash for 3 minutes at 150F (65.6 °C)
3. Rinse #1: Hot Tap water rinse for 15 seconds at 120F (48.9°C)
4. Thermal Rinse with purified water for 1 minute at 194F (90 °C)

Note: This is an A₀ of 600 which meets the minimum value for surgical instrument disinfection per ISO 15883-2

5. Dry for 5 minutes 30 seconds with a set point of 220F (104 °C)
6. After completion of an automatic wash cycle, visually inspect the tray for any remaining visible soil and contaminants. If visible soil is present, remove soil by manual cleaning, brushing, and/or repeat of automatic cycles prior to sending to sterilization.

INSPECTION, ASSEMBLY and PACKING

Note: skip step 1 and step 2 below if the reusable handle were already placed into the tray during automated washing cycle.

1. Check for integrity of tray and lid, with specific attention to support brackets to ensure they are attached securely in place.
2. Place the cleaned reusable catheter handle/guidewire* assembly in the Khelix Sterilisation Tray.
3. Secure the handle/guidewire in the support bracket as indicated by **Figure 1**, ensuring the guidewire does not kink. Handles/guidewire assemblies are limited to one per tray.
4. Place tray lid on and lock the tray.
5. Wrap the trays in a sterilisation wrap (e.g. Kimberly-Clark Kimguard One-Step Sterilization Wraps) using a simultaneous double-wrapping envelope fold technique or as per CSD protocol.

STEAM STERILIZATION

1. Place the wrapped tray into the steam steriliser.
2. The following steam sterilisation parameters were validated in an AMSCO Vacumatic "A" Autoclave:
 - Cycle Type: Dynamic Air Removal
 - Pre-vacuum pressure: 27"Hg (0.914 bar)
 - Pre-vacuum Pulses: 3
 - Dwell Temperature: 132°C
 - Dwell Pressure: 26.8 psig (1.85 bar)
 - Dwell Time: 4 minutes
 - Drying Time: 20 minutes

MAINTENANCE AND INSPECTION

The tray can be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, or mechanical failure occurs. Signs of mechanical failure include:

- Broken or cracked corners
- Broken handles

STORAGE

Store as per reprocess facility's protocol/procedure, ensure terminally steam sterilised trays placed in a horizontal position. Store in a cool, dry place between 18°C - 25°C with relative Humidity 35% -75%.

Consult wrap manufacturer for shelf life information.

WARNING

Clean tray between each subsequent usage.

WARRANTY AND DISCLAIMER

CathRx warrants that if it determines that a product was defective or faulty in materials and/or workmanship within 1 year of purchase, CathRx will, at its option, provide a replacement CathRx product or refund the purchase price of the defective or faulty product.

This limited warranty only applies if the following conditions are met:

- The product was packaged and labelled by CathRx;
- The product is returned to CathRx for evaluation and investigation within 30 days of identification of the defect,
- The product has not been repaired, altered, modified, mishandled or reprocessed inappropriately;
- The product has been used, stored, cleaned, sterilised and reprocessed in accordance with the product labelling and manufacturer's Instructions for Use; and

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