

## Instructions for Use



### Intended Use

RadelR Sterilizing Trays are intended for the protection, organization and the delivery to the surgical field of surgical instruments and/or other medical devices. They are not suitable for use in a washer disinfector, for this Altomed recommend the use of the Microwash Tray. They are also not designed to maintain sterility by themselves.

They are designed to facilitate the sterilization process when used in conjunction with a wrapping material (e.g. wrap or pouch that meets ISO 11607) or a specified filtered sterilization container system. Wrapping materials and sterilization containers are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of internal components.

Always inspect all parts of the trays for cleanliness and/or damage before use. Make sure all latches and handles are secure and in working order. If the Trays are damaged do not use, contact Altomed who will be able to replace the Tray or even the actual part if applicable (e.g. lid, base, mat, etc.). If the Sterilization Tray becomes contaminated, separate into its individual components and clean in a washer/disinfector using your standard validated cycle.

Clean the instruments to be sterilized first by washing and/or disinfecting the devices using the manufacturer supplied instructions for use. Manual cleaning may also be required if specified. Any detergents or other residues should be removed from the devices before sterilization. Instruments should also be clean and dry.

Place the instruments in the Tray and balance the contents uniformly. Complex instruments may require disassembly and extended sterilization times if specified in their instructions for use. Ensure the instruments are not touching each other and that the steam can contact all the applicable surface of all the instruments in the Tray. Do not overload the Tray or force the lids. A facility approved pouch or wrap should be used to maintain the sterility of the instruments for proper aseptic presentation to the surgical field.

Always follow the instrument manufacturer's instructions for use if their sterilization recommendations are different from these guidelines. In all instances Altomed recommends that the Instruments in the trays are sterilized according to any instrument manufacturer instructions for use.

For steam autoclaves use a standard autoclave cycle of 134°C to 137°C with a minimum 3 minute holding time following Department of Health and MHRA Guidelines where applicable. Testing was done with a selection of common surgical appliances such as reamers, drills, hammers, rasps, deriviers, chisels, awls, handpieces, rongeurs, blades, and short lumened devices. The set-up of the tray and the cycle used however should be validated prior to use.

Variables that may affect drying times include: loading density of the Tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance and others.

The sterilization Trays and inserts will also withstand exposure to Ethylene Oxide.

RadelR Sterilizing Trays have **NOT** been validated for use with flexible endoscopes, or devices with lumens or working channels longer than 10cm (3mm inside diameter). Always refer to instrument manufacturer instructions.

**DO NOT STACK** the Trays in autoclave chamber. Stacking of Trays and overloading of the Sterilizer will adversely affect sterilization and drying effectiveness.

### Notice:

- DO NOT load cases into sterilizer on sides or upside down with lid side on the shelf or cart. Load cases on cart or shelf, so that the lid is always facing upward. This will allow for proper drying. RadelR Sterilizing Trays are designed to drain in this position.
- After the autoclave door is opened, all the Trays must be allowed to cool thoroughly. Place Trays on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.
- If condensation is observed, check to ensure steps 1 and 2 were followed. In addition, verify that the steam which is being used for the sterilization processing, has a quality of more than 97%. Also, confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer recommendations.
- Silicone mat accessories should be placed in alignment with perforations in cases or Trays so that sterilant pathways are not obstructed.
- Only use Trays, mats or other accessories that have been recommended by Altomed.

The following table provides guidance on the maximum loads. Do not overload the Trays and always follow hospital procedures for maximum loading and instrument manufacturer's instructions for use.

| Tray Size            | Size Guide         | Maximum Total Weight |
|----------------------|--------------------|----------------------|
| Small Tray           | 100 x 200 x 20 mm  | 0.34 Kg              |
| Standard Tray        | 200 x 430 x 20 mm  | 0.68 Kg              |
| 1/2 Size Tray        | 180 x 180 x 100 mm | 3.6 Kg               |
| 3/4 Size Tray        | 180 x 300 x 100 mm | 5.9 Kg               |
| Full Size Tray       | 230 x 480 x 100 mm | 9 Kg                 |
| Full Size Deep Vault | 230 x 480 x 150 mm | 11.3 Kg              |

| Altomed Sterilizing Trays |                                  |  |
|---------------------------|----------------------------------|--|
| Ref                       | Dimensions                       | Description  |
| A9201                     | 150 x 50mm                       | RadelR Sterilizing Tray with Finger Mat                                    |
| A9201-7                   | 180 x 50mm                       | RadelR Sterilizing Tray with Finger Mat (Cream)                            |
| A9202                     | 150 x 50mm                       | RadelR Diamond Knife Tray (Single Knife)                                   |
| A9202D                    | 150 x 50mm                       | RadelR Diamond Knife Tray (Two Knives)                                     |
| A9203                     | 150 x 75mm                       | RadelR Sterilizing Tray with Finger Mat (Cream)                            |
| A9203-7                   | 180 x 70mm                       | RadelR Sterilizing Tray with Finger Mat (Cream)                            |
| A9210                     | 280 x 180mm                      | RadelR Sterilizing Tray with Finger Mat                                    |
| A9212                     | 180 x 50mm                       | RadelR Diamond Knife Tray (Single Knife)                                   |
| A9212D                    | 180 x 50mm                       | RadelR Diamond Knife Tray (Two Knives)                                     |
| A9214                     | 180 x 75mm                       | RadelR Sterilizing Tray without Finger Mat                                 |
| A9220                     | 380 x 225mm                      | RadelR Sterilizing Tray with Finger Mat                                    |
| A9222                     | 380 x 225mm                      | RadelR Sterilizing Tray with Finger Mat and Platform with Finger Mat       |
| A9230                     | 450 x 250mm                      | RadelR Sterilizing Tray with Finger Mat                                    |
| A9232                     | 450 x 250mm                      | RadelR Sterilizing Tray with Finger Mat and Platform with Finger Mat       |
| A9239                     | 225 x 150mm                      | RadelR Sterilizing Tray with Finger Mat                                    |
| A9240                     | 225 x 150mm                      | RadelR Sterilizing Tray Deep with Finger Mat                               |
| A9241                     | 225 x 150mm                      | RadelR Sterilizing Tray Deep with Finger Mat and Platform with Finger Mat  |
| A9242                     | 225 x 150mm                      | RadelR Sterilizing Tray with Insert and Lower Mat                          |
| A9245                     | 380 x 255mm                      | RadelR Sterilizing Tray with Base and Finger Mat                           |
| A9246                     | 380 x 225mm                      | RadelR Sterilizing Tray with Finger Mat and Platform with Finger Mat       |
| A9248                     | 380 x 255mm                      | RadelR Sterilizing Tray with Base, Finger Mat and Platform with Finger Mat |
| Spare Parts               |                                  |  |
| Ref                       | Description                      |  |
| A9201Lid                  | Lid for A9201 Tray               |  |
| A9201Mat                  | Mat for A9201 Tray               |  |
| A9203Lid                  | Lid for A9203 Tray               |  |
| A9203Mat                  | Mat for A9203 Tray               |  |
| A9210Lid                  | Lid for A9210 Tray               |  |
| A9210Mat                  | Mat for A9210 Tray               |  |
| A9220Lid                  | Lid for A9220 Tray               |  |
| A9220Mat                  | Mat for A9220 Tray               |  |
| A9222Base                 | Base for A9222 Tray              |  |
| A9222BM                   | Silicone Base Mat for A9222 Tray |  |
| A9222Insert               | Insert tray for A9222 tray       |  |
| A9222Lid                  | Lid for A9222 tray               |  |
| A9222Mat                  | Mat for A9222 tray               |  |
| A9230B                    | Base for A9230 Tray              |  |
| A9230Lid                  | Lid for A9230 Tray               |  |
| A9230Mat                  | Mat for A9230 Tray               |  |
| A9240B                    | Base for A9240 Tray              |  |
| A9240Lid                  | Lid for A9240 Tray               |  |