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Technical notice for INOTRAY cases



NON STERILE

NOT-STERIL

Language : English

General Information

INOTRAY cases developed and manufactured by Inomed Technology have to be handled, conditioned and used only by health professionals, hospital staff or people suited, trained, recognized and authorized to handle such medical devices.

It is important that users refer to Inomed Technology's document DSP4.1.7 relating to the following processes:

Material
Utilization
Warning
Cleaning and contamination
Washing and disinfection
Maintenance and manipulation of instruments
General cleaning
Sterilization

As Inomed Technology is not responsible of each hospital's handling procedures, cleaning / sterilization methods and bio-contamination levels, Inomed Technology takes no responsibility for product sterilization even if the general directives described in general note DSP4.1.7 are followed.

Device name	INOTRAY case
Application	<p>INOTRAY case is considered as accessories and allows following use :</p> <ul style="list-style-type: none"> ➤ Conditioning, storage and transport of surgical instruments and accessories ➤ Washing of surgical instruments and accessories after decontamination ➤ Sterilization of surgical instruments and accessories after washing and drying.
Classification	INOTRAY case is a class I medical device (<i>Lit. Directive 93/42/CEE</i>).
Advantages	<ul style="list-style-type: none"> ➤ INOTRAY case has been designed in such a way that users can handle it with a maximum of safety, and this thanks to the handles that are attached directly onto the case instead of onto the lid. ➤ INOTRAY case has been designed in such a way that its use is simple. ➤ INOTRAY case has been designed in order to facilitate its cleaning. As a matter of fact, recesses, slides, clasps and tangles have been reduced to its minimum.
Comments	<ul style="list-style-type: none"> ➤ Supports designed for surgical instruments are developed and manufactured according to the surgical instruments of the manufacturers or of the distributors of implant (corporate who markets the products). ➤ Inomed Technology does not take any responsibility for the capacity of surgical instruments to be efficiently sterilized. This responsibility falls to the instruments producer, and/or to the implant manufacturer and/or its distributor (corporate who markets the products). ➤ Inomed Technology's customers are responsible to forward this note to the final user of INOTRAY products. ➤ In the present note, Inomed Technology informs only on the use of INOTRAY trays and its accessories. Information and notes specific to surgical instruments fall to the instruments producer, and/or to the implant manufacturer and/or its distributor (corporate who markets the products). <p>! IMPORTANT ! In order to detect eventual sign(s) of damage, do inspect each INOTRAY product at its reception and after each use and cleaning !</p>

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I. Recommendations



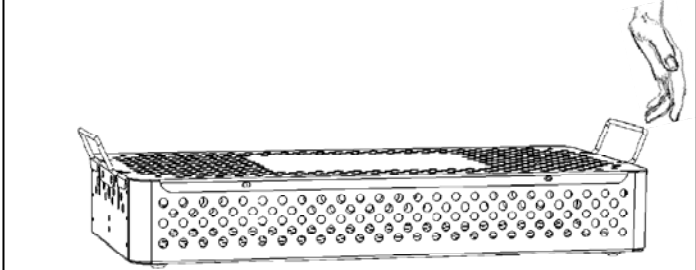
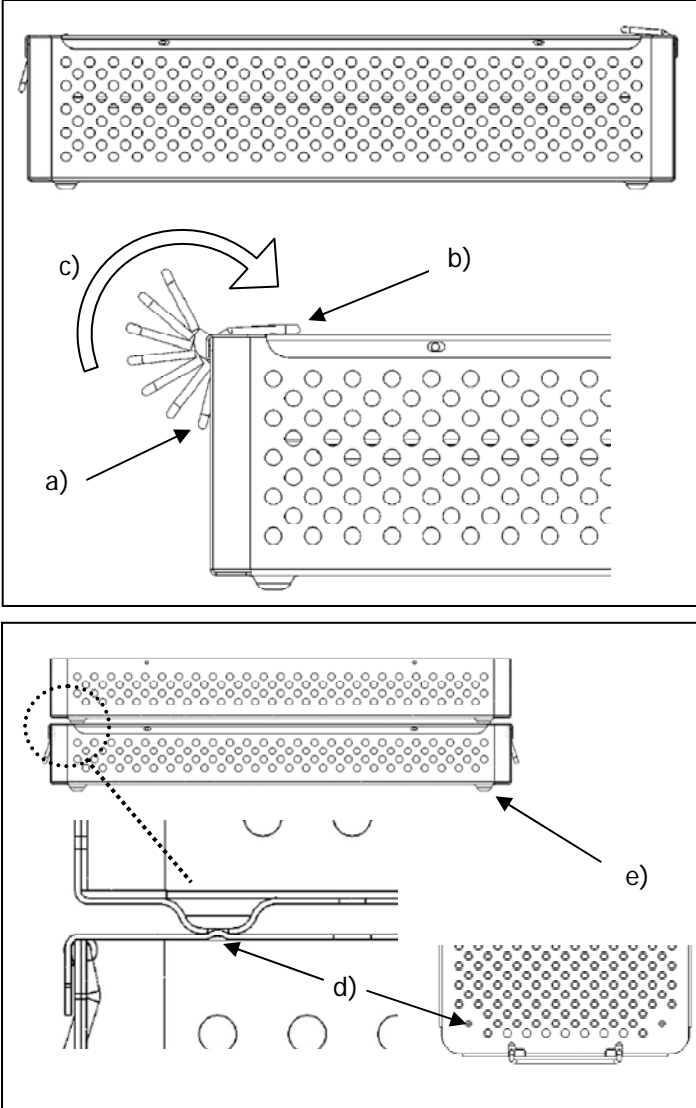
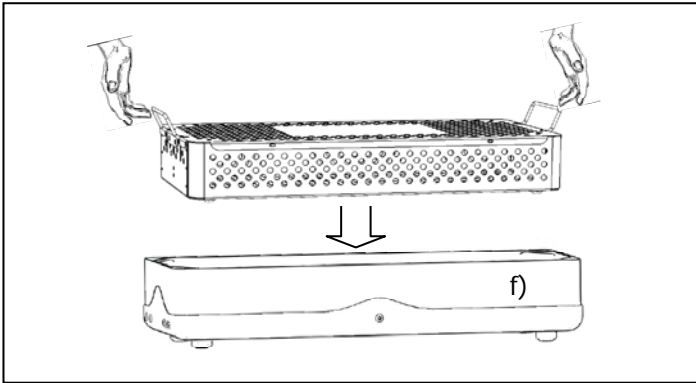
Inomed Technology recommends to :

- Place all surgical instruments on their supports inside the INOTRAY cases for washing and sterilization purpose.
- Sterilize cases and their contents through sterilization containers (read the note of containers manufacturers) during the sterilization process, although in some sterilization centers, sterile paper (read the note of the paper manufacturers) replaces the sterilization containers.
- Place all surgical instruments on their supports inside the INOTRAY cases for transport and of storage purpose.
- Decontaminate and clean all surgical instruments before putting them on their supports inside INOTRAY cases.
- Don't let INOTRAY cases fall down or be shocked in order to avoid cases and/or contents damages.
- Don't clean any silk-screened parts with detergents (acetone, thinners or derived, ...).



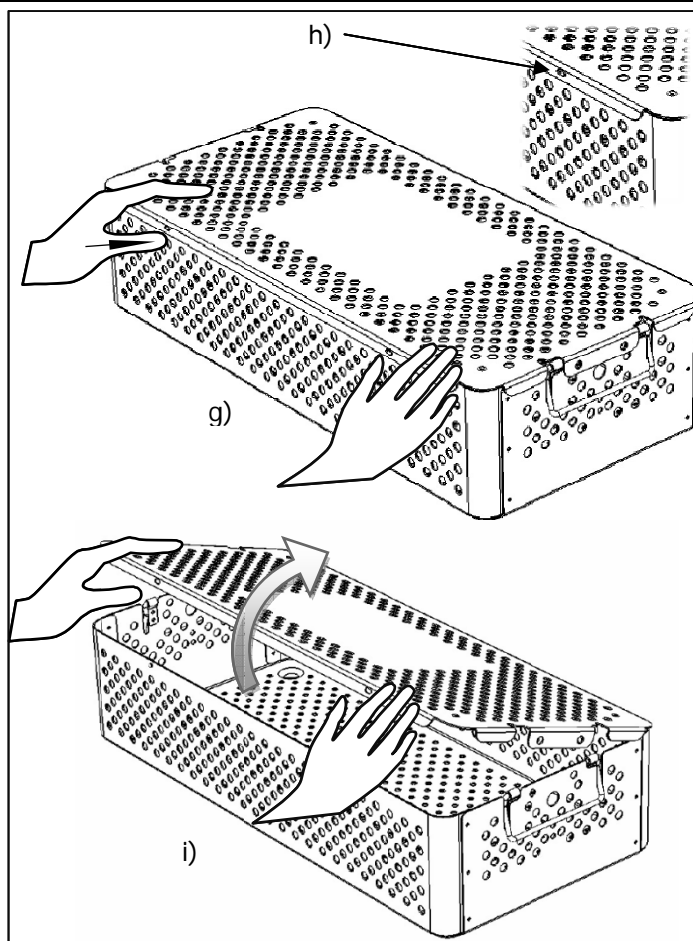
II. INOTRAY products description

General Description	Detailed description	Comments	Representation
	<ul style="list-style-type: none"> INOTRAY 2.5 INCH 	Dimensions : <ul style="list-style-type: none"> Outside length : 518 mm Outside width : 244 mm Outside height : 66 mm 	
	<ul style="list-style-type: none"> INOTRAY 3 INCH 	Dimensions : <ul style="list-style-type: none"> Outside length : 518 mm Outside width : 244 mm Outside height : 76 mm 	
	<ul style="list-style-type: none"> INOTRAY 4.5 INCH 	Dimensions : <ul style="list-style-type: none"> Outside length : 518 mm Outside width : 244 mm Outside height : 114 mm 	
	<ul style="list-style-type: none"> INOTRAY OPEN INSERT 	Dimensions : <ul style="list-style-type: none"> Outside length : 499 mm Outside width : 239 mm Outside height : 46 mm 	
	<ul style="list-style-type: none"> INOTRAY LID 	Function : The lid should perfectly close on the bases.	
	<ul style="list-style-type: none"> INOTRAY HALF-BASE 	Dimensions : <ul style="list-style-type: none"> Outside length : 230 mm Outside width : 244 mm Outside height : 76 mm 	
	<ul style="list-style-type: none"> INOTRAY CLOSED 2/3 INSERT 	Dimensions : <ul style="list-style-type: none"> Outside length : 270 mm Outside width : 237.5 mm Outside height : 68.8 mm 	

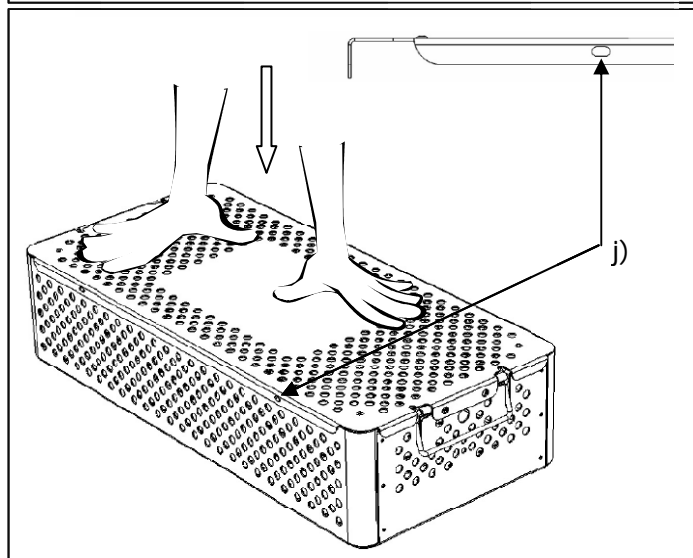
<h3>III. Transport</h3>	<ol style="list-style-type: none"> 1. Surgical instruments can be transported in INOTRAY cases when they are placed on their supports. 2. Handles attached onto the base of INOTRAY case allow its transport in full safety. 	
<h3>IV. Storage</h3>	<ol style="list-style-type: none"> 1. During the storage of INOTRAY cases, it is possible to place the handles as follow : <ol style="list-style-type: none"> a. Vertically (against the case wall) b. Horizontal (on the top of the lid) To do this, make the handles swiveling around their axis (c). 2. It is possible to stack up the INOTRAY cases for their storage. Four lid pins (d) are designed in order to allow a better stability during stacking. The INOTRAY case feet (e) come against the lid pins (d). It is also possible to stack up the INOTRAY with the handles posed horizontally on the lid (b). 	
<h3>V. Sterilization in autoclave</h3>	<p>During autoclaving, the INOTRAY cases can be placed into sterilization containers (f). When doing this, make sure that the handles are turned on the top of the lid (b).</p> <p>Inomed Technology recommends using sterilization containers for the process of sterilizing the instruments contained in the INOTRAY cases.</p>	

VI. Opening and closing of standard INOTRAY cases

1. To open standard INOTRAY cases, slightly press with the thumb on the large tray wall (g), raise up the lid at the same time (i) and then remove it away.

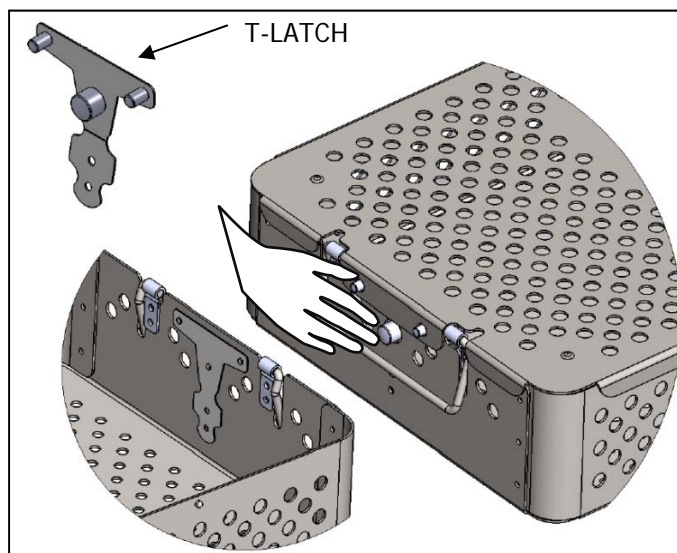
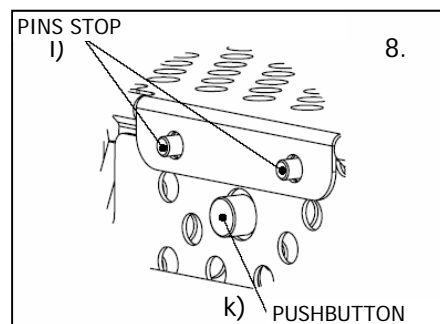


2. To close the lid on the standard INOTRAY case, place the cover upon the case and slightly press it downside. When doing this, make sure that the lid is correctly placed on the case, in particular that the lid vertical walls are located outside of the case.

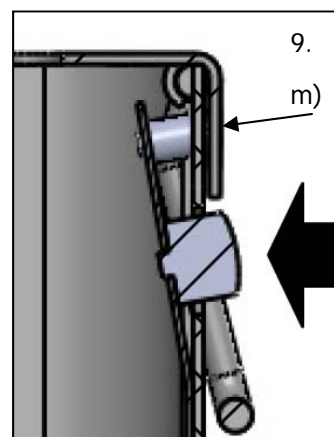


VII. Opening and closing of T-latch INOTRAY cases

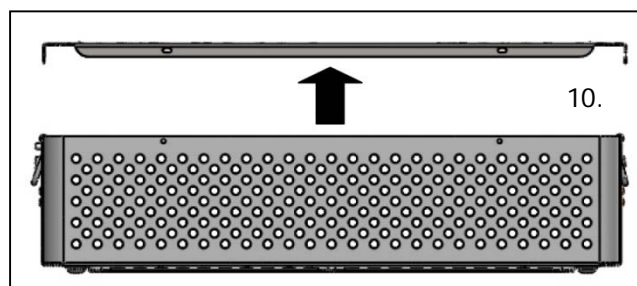
8. To open T-latch INOTRAY cases, slightly press with the thumbs on the large pushbuttons (k) of each short wall case, what releases the lid (m) from the pins stop (l).



9. While pressing on both pushbuttons (k), raise up the lid (m).



10. Now remove the lid from the case.



11. To close T-latch INOTRAY cases, place the cover upon the case and slightly press with the thumbs on the large pushbuttons (k) of each short wall case, what releases the lid (m) from the pins stop (l). Now slightly press the lid on the case.

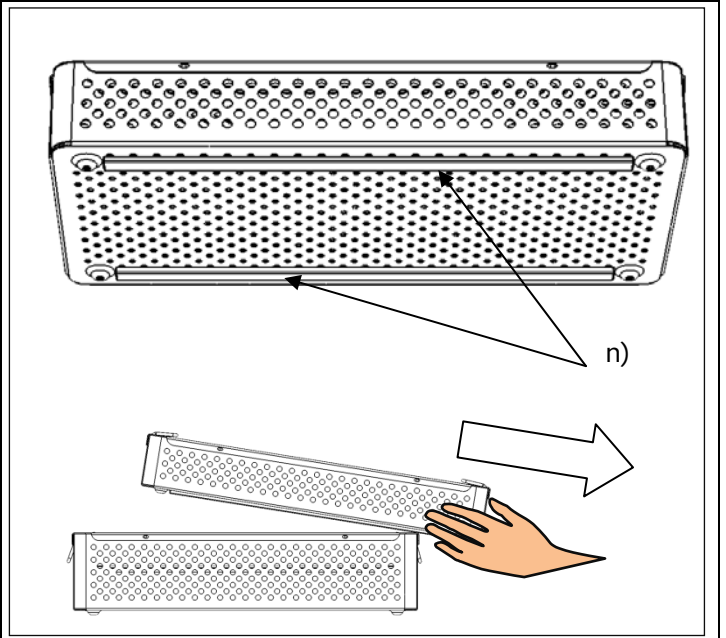
When doing this, make sure that the lid is correctly placed on the case, in particular that the lid vertical walls are located outside of the case.

VIII. Accessories

Protection skis (n)



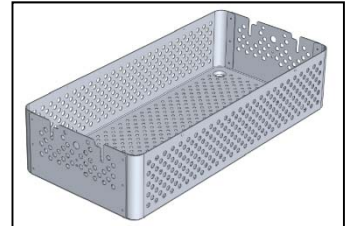
In some sterilization centers, sterile paper (see notice of the paper manufacturers) is used to wrap the cases instead of placing them inside sterilization containers.
The INOSKI protection skis (n) avoid the risks of tearing of paper during handling or wrapping processes.



IX. Materials

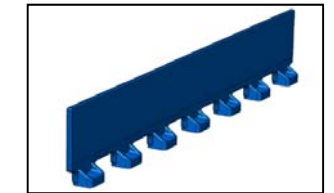
1. INOTRAY case (sheet)

Stainless steel 1.4301 (304) or equivalent



2. Bracket

PSU/PPSU



3. Screws

Stainless steel 1.4301 (304) or equivalent



4. «T-latch

Spring stainless steel 1.4310 or equivalent



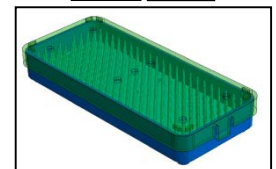
5. Pushbuttons and pins-stop

Stainless steel 1.4301 (304) or equivalent



6. INOPACK
• lid
• base
• silicone mat

PSU or PPSU
PSU or PPSU
Silicone



7. Protection skis

PA or PSU



8. Post

POM C/ PPSU/ Polypropylene

