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Owner's manual

Medi-X-TABB™ Mold

For use in prescription pharmacy compounding only, in accordance with applicable law. Medisca makes no warranty or representation regarding the use of this product or fitness for any particular purpose, and any such use is entirely the responsibility of the pharmacist in the exercise of his/her professional expertise and judgment. Accordingly, in no event will Medisca be liable for any damages from the use or misuse of the product. Purchaser's sole remedy in the event of product defect or other damages shall be the refund of the purchase price of the product.

This manual is intended for use by qualified compounding personnel engaged in the service, inspection, maintenance and handling of the equipment.

Version 2, January 2025

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1 Medi X-TABB™ Mold

The Medi X-TABB™ Mold is a versatile and innovative system enabling high efficiency prescription compounding for both oral disintegrating tablets (ODTs) and troches. The Medi X-TABB™ System was developed to increase efficiency, control, containment, and compliance as the system can easily be used under a containment hood while compounding without the need of a convection oven. The Medi X-TABB™ System is constructed of durable aluminum hard coated with the latest US and EU contact approved non-stick technology. All components, instructions, and operation of this System are patent pending.

This Owner's Manual has been compiled with details regarding proper care and maintenance to enable safe operation. Before operating, familiarize yourself with the contents of this user manual to ensure safe operation. When the system is in operation, the owner must ensure that operators of this system have read and understand this user manual.

Confirm all components are present prior to system use. A components checklist should be included with each system. To guarantee personal safety, the following instructions must be carefully observed:

1-1 Work area

- Keep the work area clean and well lit.
- Place the mold on a flat, dry, non-combustible surface. The underside of the Heat Plate will get hot when in use, precaution must be taken to not touch the underside of the heated plate when in use.
- Always operate system on a non-combustible/non-meltable surface (i.e., heat rated laboratory counter or surface). Take a note of operating temperature and surface heat rating when in use.
- Do not operate in explosive atmospheres, such as in the presence of flammable liquids, gases or dust. Do not place flammable materials in, on or around the system.

1-2 Electric safety

- The power plug must match the outlet and the outlet must be appropriately grounded. Do not modify the plug in any way. Do not use adapter plugs or extension cords.
- Do not expose the mold to wet conditions. As with any piece of electrical equipment, operating the machine when wet or near liquids will increase the risk of electrical shock.
- Do not abuse the power cord. Never use the cord for carrying, pulling or unplugging the mold. Keep cord away from: heat, oil, sharp edges or moving parts. Damaged or entangled cords increase the risk of electrical shock.
- For installation and maintenance work, the machine must always be disconnected from the main power connection. The machine operator must avoid any contact with the electrical parts.
- All safety and protective measures and facilities must have been applied and must be maintained in accordance with IEC instructions (International Electrotechnical Commission).

1-3 Personal safety

- The equipment may only be set up, started or serviced after gaining familiarity with the Owner's Manual.
- During operation of the equipment, do not permit any work method that hinders the safety of the products, equipment and personal. Do not use the mold when you are tired or under the influence of drugs, alcohol, or medication.
- Recommended to use only ground fault protected outlets/circuit (GFCI) before plugging in.
- Components may become hot during use. Wear appropriate hand protection (hot pads) when handling.
- In case of malfunction, immediately stop the unit.

1-4 System use and care

- Always unplug from the power source when not in use or before performing any cleaning or maintenance.
- The mold and components require periodic cleaning. Check for surface debris, dust, or binding of moving parts, broken parts and any other condition that may affect the operation. Do not operate a damaged mold.
- The socket-outlet shall be installed near the equipment and shall be easily accessible for the user.
- Never use harsh solvents when using or cleaning the system and components. We recommend household dishwashing liquid. Do not use acidic or caustic cleaning solutions. Do not clean with abrasive cloth, gritty materials, or steel wool. Use only plastic brushes or nylon pads.
- Never use metal utensils when using the mold. Use only soft plastic tools that are non-abrasive to the specialized non-stick surface coatings.
- The mold may be cleaned with isopropyl alcohol. If needed, we recommend wiping with a cloth dipped in isopropyl alcohol, then immediately wipe dry with a clean cloth.
- The mold is a series of precision machined/coated components that with proper care is designed for many years of service. Take care when handling components so they do not come in contact with other sharp or blunt objects that may damage or scrape the coatings. Do not drop or apply excessive force on components that may cause warping or component deformation. Refusing to take proper care of as outlined in this manual may result in costly component replacement.
- The mold is **NOT** dishwasher safe. Hand wash only with mild detergent and water. Do not use abrasive scrubbers or pads, bleach, acids, or harsh solvents. The components are machined from a high-grade non-corrosive aluminum plated with a specific non-stick hard coating designed for hand wash cleaning only. Common harsh dishwasher detergents and prolonged high temperatures will drastically reduce the life of the coating and potentially cause system component harm. May be dried with the use of a portable air dryer. The Heat Plate is not submergible.

1-5 Storage

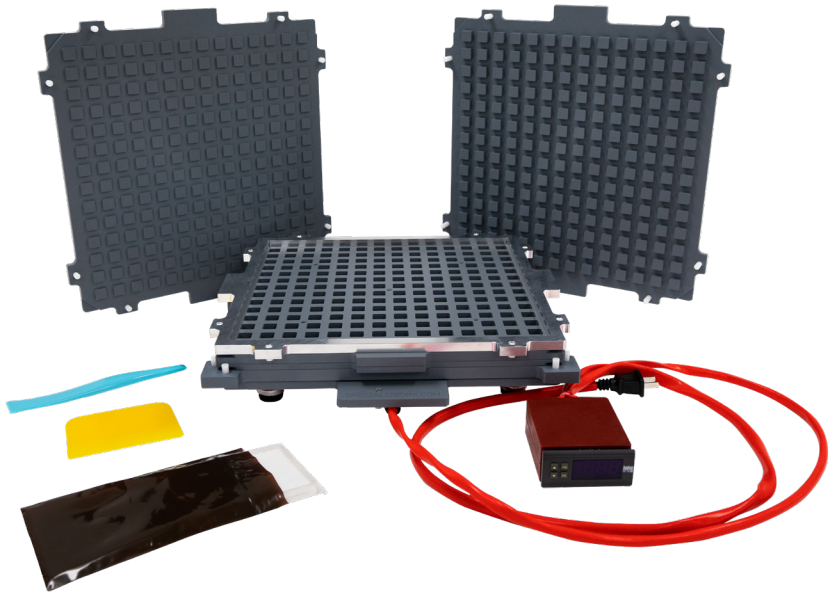
Store the mold only under following conditions:

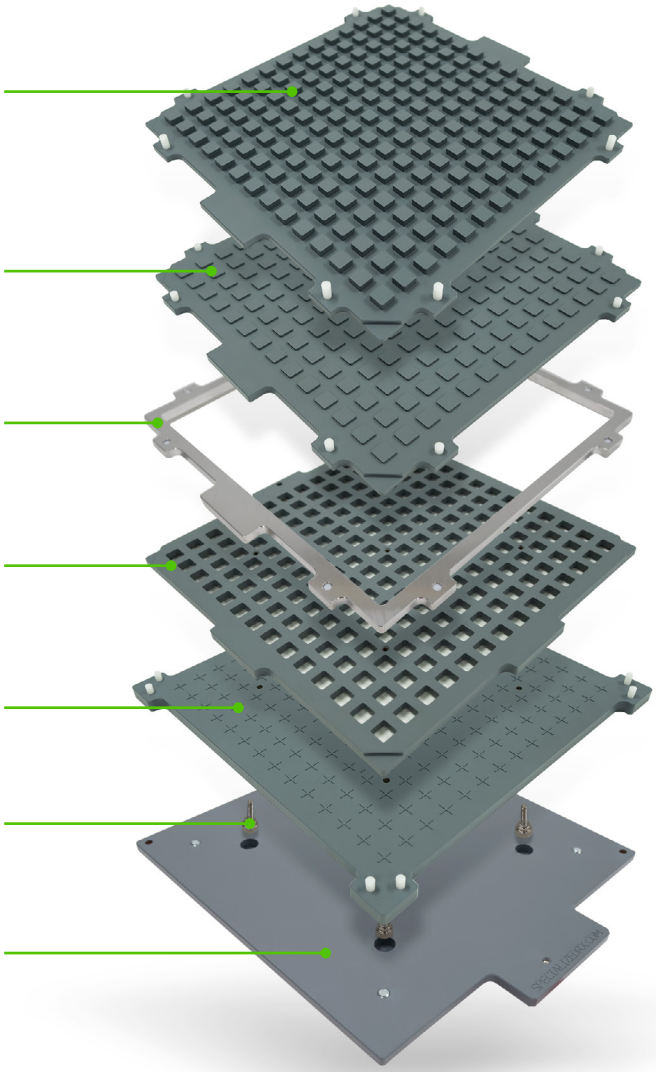
- The device must only be stored under dry conditions at ambient temperature.
- Do not store outside or in a high humidity environment for potentially damaging electrical components.
- Keep dry and dust-free.
- Protect from excessive prolonged heat, i.e., radiator/heat source.

1-6 Technical specifications

- **Voltage:** 120 V (US)
- **Power Consumption (max.):** 270 W (US)
- **Power Outlet:** 15-amp minimum. GCFI outlet/circuit recommended
- **Power Requirement:** Most common breakers are at 15-amps (supplying 1800 W). The next most common breaker size is 20-amps (supplying 2400 W).
- **Power Cable:** Supplied with US 2-lead plug, 1-meter (39") cord from controller. Customized international electrical systems (plugs, controller, and heat plate) available upon request.
- **Dimensions:** Approx. 310mm x 310 mm (13" x 13")
- **Heater Rating:** 4 Watts/sq. inch heats up to 60C in 30 seconds
- **Silicone Heater:** 3M adhesive backing equipped with NTC 100K thermistor (Beta 25/50 3950K-1%) as temperature control sensor which is supported directly by Marlin firmware.
- **Height:** Approx. 76 mm (3")
- **Efficient Heat Transfer:** -50 °C to ~260 °C (-58 to 500 °F) with option to control temperature accuracy between 1.0 and 0.1 degrees.

1-7 Components





Ejector Plate
(Sold separately, 5622)

RDT Tamper Plate
(5629)

Powder Dam
(Sold separately, 5625)

RDT Cavity Plate
Without Overflow
(196 cavities of 1 mL)
(5628)

Quarter Score Plate
(5627)

Stainless Steel
Thumb Screws
(5619)

Heat Plate with
Digital Controls
(5626)

Scraper Spatula (5620)

Scraper and Pry Tool (5621)

Blister Packs,
30 Cavities
(Sold Separately, 5632)

1-8 Additional accessories (Sold separately)

- Sieve, 40 Mesh, Brass, 8" Diameter (5956)
- Sieve Receiver Pan, Brass, 8" Diameter (9652)
- Hot Hand® Protector, Silicone Rubber, -70 to 500 °F / -57 to 260 °C, Red (7315)
- Blister Packs, 30 Cavities, Medi X-TABB™ (5632)

1-9 Digital temperature controller and settings

Basic settings

1 Set the target temperature

- Press the "SET" key once to enter the TEMPERATURE setting mode.
- Press the "UP" key (▲) or the "DOWN" key (▼) to raise or lower the numbers until the desired temperature is reached. Press once to change by 1 degree or press and hold to skip degrees and change quickly. The default temperature is 55 °C (63 °F).
- Press the "SET" key again to finish.

2 Turn On/Off

- Press and hold the "RST" key for 3 seconds to power off.
- Press "RST" key once to power on.

3 System menu settings

- Press and hold the "SET" key for 3 seconds to enter the SYSTEM MENU setting mode.
- Press the "UP" (▲) or "DOWN" (▼) key to find the parameters to be adjusted. See the table in article 4 for an explanation of these options.
- Press the "SET" key once you have selected the correct option. Then, press "UP" (▲) or "DOWN" (▼) to change the value.
- Press the "SET" key again to confirm the change and return to the menu.

4 System menu options

Symbol	Meaning	Example	Notes
HC	Heating / Cooling	H = Heating Mode / C = Cooling Mode	—
D	Delay Control	When the target temperature is set to 100 °C and "D" is set to 5, the controller ceases output at 105 °C and resumes output at 95 °C.	Default is 1°
LS	Lowest Setting	Lowest limit of temperature setting.	—
HS	Highest Setting	Highest limit of temperature setting.	—
CA	Temperature Compensation	When the temperature value measured from the sensor is 100 °C, the controller will display 101 if "CA" is set to 1, 102 if "CA" set to 2, or 99 if "CA" set to -1.	Default is 0
PT	Postpone Startup	—	—
AH	Alarm, High Temperature	Alarm will sound when the measured temperature is higher than the target temperature. Screen display will alternate between "H" and the current temperature.	Default is on. Set to 0 to turn off
AL	Alarm, Low Temperature	Alarm will sound when the measured temperature is lower than the target temperature. Screen display will alternate between "L" and the current temperature.	Default is on. Set to 0 to turn off
AT	Timer	Set a time in minutes for the controller to cease output.	Not visible until activated. See "**Advanced settings**"

Advanced settings (AS)

1 Important note

- Once AS is entered, the controller is restored to COOLING MODE, even if no change is made.
- Please refer to "**Basic settings**" to set the HC value to H for HEATING MODE after you have finished using AS and restarted the controller.
- All other values under "**Basic settings**", such as target temperature, are also restored to default settings after using AS and restarting the thermostat.
- It is important to reset the HC value and restore any changes made under "**Basic settings**" after using AS and restarting. Failure to do so may result in damage to the heating element, premature failure of the equipment, and/or risk of fire.

2 What can “AS” do?

- Activate the timer function
- Change display from Celsius to Fahrenheit
- Adjust control accuracy between 1 and 0.1 degree

3 How to enter “AS” and make changes

- Press and hold the “SET” key and the “UP” key at the same time for 3 seconds to enter AS.
- Press the “UP” (▲) or “DOWN” (▼) keys to find the parameters to be adjusted. See the table in article 5 for an explanation of these options.
- Press the “SET” key once you have selected the correct option. Then, press“UP” (▲) or “DOWN” (▼) to change the value.
- Press the “SET” key again to confirm the change and return to the menu.
- Press the “RST” key to exit. The controller will restart automatically.

4 Timing function

- The “AT” (Timing Function) option appears under the SYSTEM menu when “DL” is set to ON using advanced settings.
- Time is set in minutes. The default value is 0, which means the timing function is inactive.
- When using the timing function, the controller will only start output when the “RST” key is pressed. For example, if a value of 120 minutes is set, heating will only start when “RST” is pressed. When 120 minutes is up, the controller will stop heating but remain on. The screen will alternate between the current temperatures and “OFF”.
- Resume heating by pressing the “RST” key once.
- In working mode, the screen will alternate between the current temperature and the time remaining.

5 Advanced settings options

Symbol	Meaning	Example	Notes
C\F	Sets display to Celsius or Fahrenheit	—	—
ST	Adjusts accuracy of control	When set to 01, you can change the temperature by 0.1 degree at a time.	01 = 0.1 degree, 10 = 1 degree (10 is default)
DL	Timing function	—	OFF is default ON activates timing function (AT) under SYSTEM MENU
U	Timing mode	—	OFF = Time starts when target temperature is reached ON = Time starts when controller begins heating

2 Medi X-TABB™ Mold (Tablet system)

2-1 Components

- Heat Plate with Digital Controls, Medi X-TABB™ (5626)
- Quarter Score Plate, Medi X-TABB™ (5627)
- RDT Cavity Plate Without Overflow (196 cavities of 1 mL), Medi X-TABB™ (5628)
- RDT Tamper Plate, Medi X-TABB™ (5629)
- Scraper Spatula, Medi X-TABB™ (5620)
- Scraper and Pry Tool, Medi X-TABB™ (5621)
- Stainless Steel Thumb Screws, Medi X-TABB™ (5619)
- Ejector Plate, Medi X-TABB™ (Sold Separately, 5622)
- Heat Deflector Plate, Medi X-TABB™ (Sold Separately, 5624)
- Powder Dam, Medi X-TABB™ (Sold Separately, 5625)

Note: Heat Plate should be as level as possible when using the Medi X-TABB™ Mold.

To level the Heat Plate

1. Determine which of the four leveling feet needs to be raised or lowered. With a 1/2 inch wrench, loosen the leveling nut(s) and adjust the appropriate leveling mount(s) attached to the Heat Plate. The leveling mounts should never be adjusted so the bolt extends beyond the top surface of the Heat Plate.
2. Once level, carefully snug the 1/2 inch nuts back up against the stainless washers.

Attention: Do not over tighten the leveling nuts. Doing so could compromise the integrity of the silicone heating pad.

2-2 Preparatory instructions/Calibration

Formulas should be calibrated and verified prior to using this mold for finished prescriptions. It is recommended that the user compound and document their calibration blanks specific to their techniques and bases used. As a guide, Medisca has provided the below calibration targets for reference. Mold calibration target per cavity:

- Medi X-TABB™ Base (per Medisca Medi X-TABB™ Mold procedure): 765 mg +/- 20 mg
- Medi-RDT™ Base (per Medisca Medi X-TABB™ Mold procedure): 725 mg +/- 20 mg

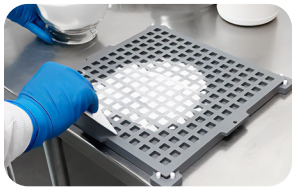
1. Weigh API(s), Medi X-TABB™ or Medi-RDT™ Base and other formulation ingredients.

   Note: The API used in formulation must be thermally stable from 80-110 °C. Refer to drug reference guide or call compounding service department.

   - To account for processing error, it is suggested to measure an additional 5-9% of the required ingredients to compound a prescribed formula.
   - The amount of base will vary with the API content. Refer to sample formula to correctly determine the required amount of base and other formulation ingredients.
   - Under containment hood, preheat the Heat Plate to 80-110 °C based on formula preference.

2. Prepare and mix all ingredients together following the formula specific steps.

2-3 Filling RDT Cavity Plate



1. On a flat, level, clean surface, fill the cavities of the mold with the powder mixture. To fill the mold cavities, pour approximately half of the powder mixture and spread over the cavities with the use of a Scraper Spatula. Add more powder mixture as needed to fill all the cavities. Remove excess powder mixture into a weigh boat and reserve it. It is important to completely fill and level the cavities. The use of the Medi X-TABB™ Powder Dam (sold separately) will help reduce time spent on the powder spreading process.

2. Compact the powder in the cavity with the RDT Tamper Plate. Remove the RDT Tamper Plate and fill the cavities with a portion of remaining powder mixture from the previous step. Remove excess powder and reserve it. Compact again with the RDT Tamper Plate. Generally, 3 filling and tamping process repetitions are appropriate in order to completely fill the cavities in preparation for the heating cycle.

2-4 Heating

Refer to "**1-9 Digital temperature controller and settings**". It is recommended to pre-heat the Heat Plate to desired working temperature prior to use for consistency in the compounding process.

1. Place the filled plates (RDT Cavity Plate and Quarter Score Plate) on the Heat Plate preheated at the desired temperature per your formula requirements (i.e.110 °C for 15 minutes or 90 °C for 30 minutes, etc.). Invert the RDT Tamper Plate and place the top side down over the RDT Cavity Plate to contain the heat to the RDT Cavity Plate. The heating time must be very specific (if necessary, use a timer for this procedure) factoring in the initial time it will take to acclimate the Quarter Score Plate and RDT Cavity Plate to achieve thermal equilibrium with the Heat Plate at the desired temperature (additional 2-5 minutes).

2. Once the heating cycle has finished, carefully remove the RDT Tamper Plate with the use of Hot Hand® Protector. Then carefully remove both the Quarter Score Plate and RDT Cavity Plate (together) from the Heat Plate and allow to cool slightly at room temperature (2-5 minutes) before separating the plates to assure the RDT's have set before removal.

2-5 Removal

Depending on the formula and heating parameters used to compound tablets, when the plates are separated, the finished tablet may either stay on the Quarter Score Plate or in the RDT Cavity Plate, or a combination of both.

For this step, user preference will vary for tablet removal.

1. The plates can be separated while fully cooled and individual tablets can be removed from the RDT Cavity Plate or while the plates are still warm, and the tablets have been allowed to cool for 3-5 minutes.

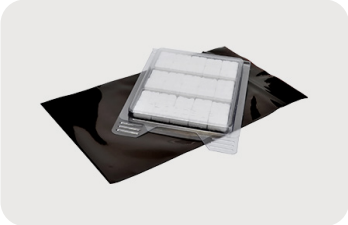
2. Separate the RDT Cavity Plate from the Quarter Score Plate using the RDT Cavity Plate corner tab features and Scraper and Pry Tool. Tablets can be removed by either of the two methods beside.

3. Allowing the RDT Cavity Plate to fully cool at room temperature, then pressing each tablets carefully out of the RDT Cavity Plate. Tip: To help with tablet removal from the RDT Cavity Plate, tablets can be partially removed before fully cooled by inverting the RDT Tamper Plate (clean and free of powder residue) with white embossed peg facing up on a flat surface, aligning the RDT Cavity Plate (score marks facing down) and gently pressing the RDT Cavity Plate down. Cool at room temperature, then remove tablets.

4. Using the Ejector Plate placed on a flat surface with embossed peg facing up, align the RDT Cavity Plate over the Ejector Plate and gently press down releasing the tablets from the RDT Cavity Plate. Allow tablets to fully cool to room temperature before handling.

   Please note that it is recommended to allow tablets to fully cool for 15-30 minutes at room temperature and relative humidity before handling or packaging.

2-6 Blister packaging



For tablet packaging:

1. Transfer the oral tablets into a Blister Pack.
2. Attach tamper label if appropriate, slide into labeled blister sleeve or light resistant zip-lock bag. Blister Packs, 30 Cavities, Medi X-TABB™.

2-7 Cleaning and maintenance

Notes:

- The mold is **NOT** dishwasher safe. Hand wash only with mild detergent and water.
- Do not use abrasive scrubbers or pads, bleach, acids or harsh solvents. The components are machined from a high-grade non-corrosive aluminum plated with a specific non-stick hard coating designed for hand wash cleaning only.
- Common harsh dishwasher detergents and prolonged high temperatures will drastically reduce the life of the coating and potentially cause system component harm. May be dried with the use of a portable air dryer. The Heat Plate is not submergible.

Steps:

1. Soak the plates in warm water-soap solution for a few minutes to facilitate cleaning.
2. Wash the plates using warm water, liquid soap and a soft brush or sponge.
3. Rinse and drain off all product contact plates.
4. Use 40% alcohol solution for final wipe down.
5. Allow to dry.

ATTENTION: Avoid use of metal utensils (spoon, spatulas, scrapper, brush, etc.) and cleaning aids with abrasive surface at any time due to potential risk of damaging coating of the molds.

3 Medi X-TABB™ Mold (Troche system)

3-1 Components

- Heat Plate with Digital Controls (US Electric), Medi X-TABB™ (5626)
- Quarter Score Plate, Medi X-TABB™ (5627)
- RDT Cavity Plate Without Overflow (196 cavities of 1 mL), Medi X-TABB™ (5628)
- Scraper and Pry Tool, Medi X-TABB™ (5621)
- Stainless Steel Thumb Screws, Medi X-TABB™ (5619)
- Ejector Plate, Medi X-TABB™ (Sold Separately, 5622)
- Troche Cavity Plate with Overflow (196 cavities of 1 mL), Medi X-TABB™ (Sold Separately, 5623)

3-2 Preparatory instructions/Calibration

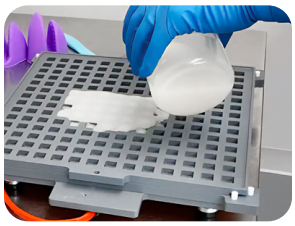
Formulas should be calibrated and verified prior to using this system for finished prescriptions. It is recommended that the user compound and document their calibration blanks specific to their techniques and bases used.

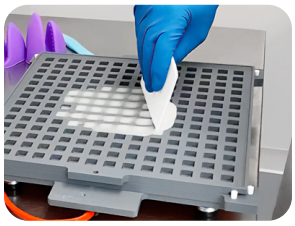
3-3 Heating

Refer to "**1-9 Digital temperature controller and settings**". It is recommended to pre-heat the Heat plate to desired working temperature prior to use for consistency in the compounding process.

3-4 Filling RDT Cavity Plate

1. It is recommended to secure the RDT Cavity Plate to the Quarter Score Plate with the five (5) Stainless Steel Thumb Screws provided with the system. This will aid in reducing the excess flashing volume between the two plates.
2. With the plates secured together with thumb screws, place them on the base Heat Plate and allow them to achieve thermal equilibrium.
3. Once the troche ingredients are ready to pour, pour the mixture into the cavities and spread evenly with the soft plastic Scraper Spatula provided until every cavity is level with the plate surface and no residual mixture is present on the surface.
4. Once filled and level, remove the connected plates from the Heat Plate to cool and disconnect the Heat Plate plug from the outlet. The ideal temperature to start cooling troches to prevent surface contractions is just above the melting temperature of the troche base used.
5. It is recommended to allow troches to cool at room temperature.





3-5 Removal

Once troches have fully cooled, they can be removed from the plates.

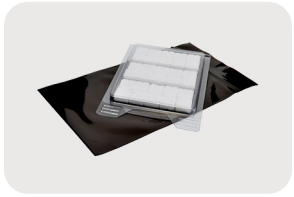
1. Remove all Stainless Steel Thumb Screws.
2. With the plates on a flat surface, using the Scraper and Pry Tool insert under corner feature between plates and gently pry plates apart moving from corner to corner. Take care to not apply excessive force to pry plates as this could damage RDT Cavity Plate.

   Use only plastic tools when working with the Medi X-TABB™ Mold to prevent damaging the non-stick coating.
3. Once plates are separated, the individual trochees can be pushed out of the RDT Cavity Plate.

   Note: For increased efficiency in removing troches from the RDT Cavity Plate, see optional Ejector Plate (sold separately).

3-6 Blister packaging

For finished troche packaging, transfer the troches to the 30 count Medi X-TABB™ Blister Packs and insert into labeled blister sleeve or light resistant zip-lock bag.



3-7 Cleaning and maintenance

Notes:

- The mold is **NOT** dishwasher safe. Hand wash only with mild detergent and water.
- Do not use abrasive scrubbers or pads, bleach, acids or harsh solvents. The components are machined from a high-grade non-corrosive aluminum plated with a specific non-stick hard coating designed for hand wash cleaning only.
- Common harsh dishwasher detergents and prolonged high temperatures will drastically reduce the life of the coating and potentially cause system component harm. May be dried with the use of a portable air dryer. The Heat Plate is not submergible.

Steps:

1. Soak the plates in warm water-soap solution for a few minutes to facilitate cleaning.
2. Wash the plates using warm water, liquid soap and a soft brush or sponge.
3. Rinse and drain off all product contact plates.
4. Use 40% alcohol solution for final wipe down.
5. Allow to dry.

ATTENTION: Avoid use of metal utensils (spoon, spatulas, scrapper, brush, etc.) and cleaning aids with abrasive surface at any time due to potential risk of damaging coating of the molds.

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For more information

USA 1-800-932-1039 medisca.com | CAN 1-800-665-6334 medisca.ca