

OVERVIEW

Read the Before You Begin section on page 11 of the ProFiller 3700/3800 Manual v 1.2.1 before using this machine.

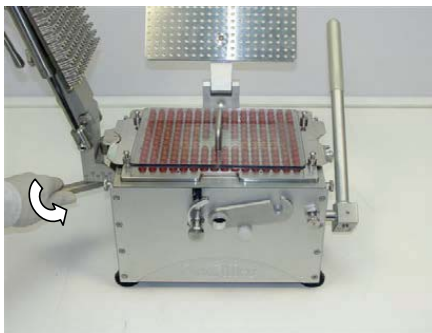
A. ORIENTATION OF OUTER CAPSULES

Orient the capsules as shown in the ProFiller 3700/3800 Manual v 1.2.1 Operating Instructions for Orientation, page 12 steps 1-9 using the Orienter and Caps Tray for the outer capsule size.

B. SEPARATION OF CAPSULE CAPS AND BODIES



1. Make sure Cam Handle is at 0° on cam indicator. Place loaded Caps Tray with Push Plate onto Filler.



2. Pull Cam Handle towards you until you feel a noticeable resistance, securing capsule bodies in Filler.



3. To separate size AAel capsules, see Inset 1 on next page. For other capsule sizes, **slowly** push down Lifting Handle just until capsules separate. As soon as you begin to feel resistance, **slowly** release the Lifting Handle. This resistance occurs as the Bottom Plate begins to lift the capsule bodies. Continuing past this point will cause the capsule bodies to be lifted out of the Filler. See *Capsule Separation Tip* below.

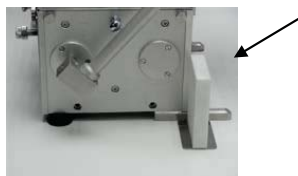
Capsule Separation Tip

If more than 1 or 2 caps fail to separate from bodies in step 3 when filling sizes AAA AA, AAel or A, or if more than 8 to 10 fail to separate for sizes B or D, Cam Handle should be rotated to a higher degree on Cam indicator in step B2. When rotating Cam Handle, there should be enough pressure on capsule bodies to hold them inside Filler, but not so much that capsules are squeezed to an oval shape.

INSET 1 (for Step 3): SEPARATING SIZE AAel Capsules



a. The Body Ejector Stopper stops motion of the Lifting Handle after size AAel capsule separation to prevent ejection of capsule bodies from the Filler.



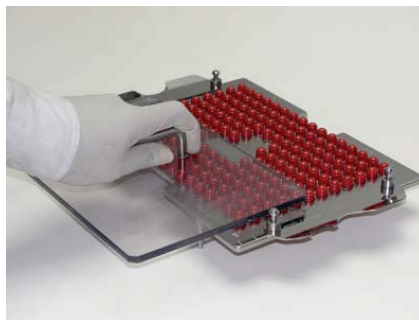
b. Before Separation (Step 3), align front of Body Ejector Stopper with back of Base Frame as shown in the photo.



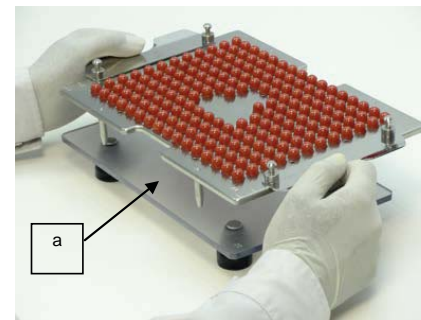
c. In Step 3, press the Lifting Handle until it touches the Body Ejector Stopper, then release it slowly. After separation, remove the Stopper Block before locking the capsules.



4. Lift Caps Tray with the Push Plate **slowly**.



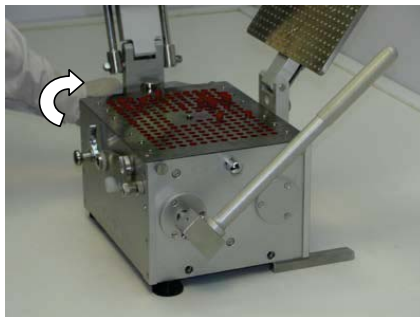
5. Set Caps Tray with Push Plate on table. Slide Push Plate off Caps Tray to avoid lifting caps due to static.



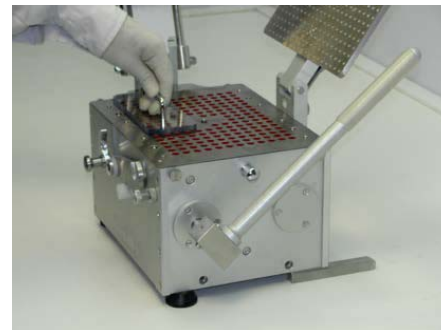
6. Place Caps Tray on Unseparated Capsule Ejector Plate (a).



7. Capsules that have not separated will be pushed higher up in Caps Tray. Remove these capsules and separate the cap from the body by hand. Insert the cap back in the Caps Tray and insert the body into the Filler.



8. Push Cam Handle away from you to return Cam Indicator to 0°. This allows bodies to drop.



9. Use smaller OE Push Plate to seat bodies in Filler. See *Capsule seating Tips* below.

Capsule Seating Tips

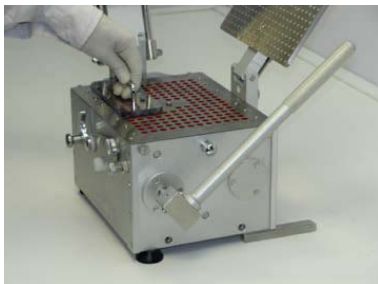
After using the Push Plate, all capsule bodies may not sit at an even level in Filler. This is because of variation in capsule body shape (round to slightly oval), diameter (capsule bodies vary by 0.12 mm within the same batch for most manufacturers), length of capsule body (can vary up to 1 mm within the same batch), type of capsule (gelatin, hpmc, other) and manufacturer. After the first tamp or vibration cycle, the capsule bodies will be pushed down to the Bottom Plate. The top of the bodies still may not all be level due to capsule body length variation. There is no effect on fill weight variation due to the initial height of the capsule body in the Filler.

We recommend that the top of the capsule bodies sit 0.5 – 1 mm below the top of the Filler. Positioning bodies exactly even with top of Filler will lower the average fill weight, and could result in some bodies sticking out above the Body Sheets due to capsule length variation. To adjust capsule body height, see page 14 Adjust Bottom Plate Height.

INSERTING TABLETS INTO OUTER CAPSULES

The number of holes will differ by size. This does not affect the instructions for use except where noted.

Capsule Size	Number of Outer Capsules in Filler	Number of Holes in Attachment	Number of Cycles
A, B, D	270	90	3
AA, AAel	180	180	1
AAA	120	120	1



1. These instructions begin after outer capsules are oriented, separated, and seated into Filler.



2. Place the OE Guide Tray on the Filler.



3. Pour tablets onto ATF and tilt in all directions moving capsules into slots.



4. Tilt the ATF to pour off excess tablets.



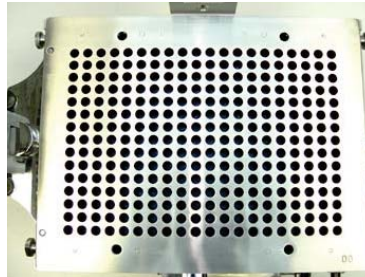
5. Place ATF locating studs into front holes of OE Guide Tray.



6. Press release bar to drop the tablets into the capsules.



7. For sizes A, B and D only, remove ATF and repeat steps 3-6 except in step 5 place the ATF locating studs into the second holes of OE Guide Tray. Repeat steps 3-6 a third time, placing ATF studs into third holes in step 5.



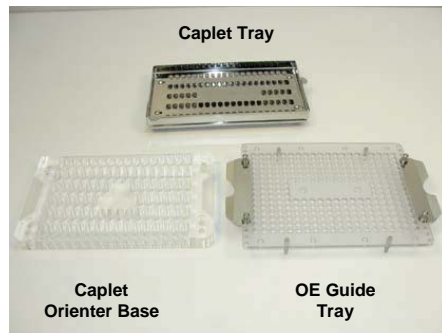
8. For all sizes, remove ATF and OE Guide Tray. Verify that tablets are inside all capsule bodies.

Tip: To avoid tablet rattling, fill capsules with excipient.



9. Continue with "Operating Instructions" in your ProFiller 3700/3800 Manual. Begin with "Filling Capsules" if adding an excipient (page 18 in Manual v 1.2.1), or continue with "Locking Capsules" to lock the outer capsules (page 20 in v 1.2.1).

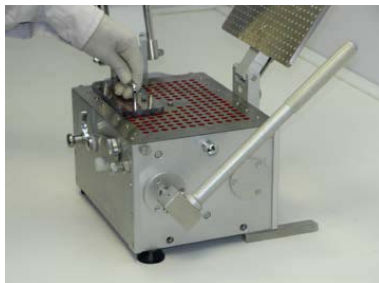
PARTS IDENTIFICATION - CAPLET-IN-CAPSULE ATTACHMENT (ORDERED SEPARATELY)



Filling caplets inside capsules can be done using the custom-made Caplet Fill Attachment (ACF). The outer capsules are oriented and separated as usual. The caplets are inserted into the open capsules, then the outer capsules are locked. To avoid rattling, the outer capsule can be filled with excipient before locking.

Batch Sizes			
The number of holes will differ by size. This does not affect the instructions for use except where noted.			
Capsule Size	Number of Outer Capsules in Filler	Number of Holes in Attachment	Number of Cycles
A, B, D	270	90	3
AA, AAel	180	90	2
AAA	120	60	2

INSERTING CAPLETS INTO OUTER CAPSULES



1. These instructions begin after outer capsules are oriented, separated, and seated into Filler.

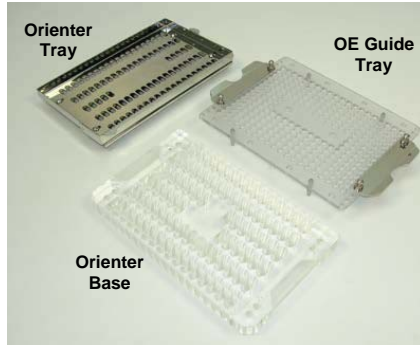


2. Place the OE Guide Tray onto the Filler. Steps for caplet orientation are similar to capsule orientation.



3. Place the Caplet Orienter Base on the OE Guide Tray. Align the front edge of the Caplet Orienter Base with horizontal line I on OE Guide Tray. Align the right edge of the Caplet Orienter Base with the right edge of the OE Guide Tray.

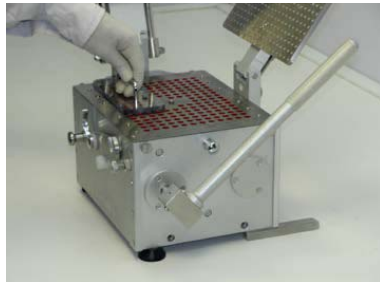
PARTS IDENTIFICATION - CAPSULE-IN-CAPSULE ATTACHMENT (ORDERED SEPARATELY)



Filling capsules inside larger capsules can be done using both the ProFiller 3700 (sizes 00-5 only) and the ProFiller 3700OE (sizes AAA-D). The outer capsules are oriented and separated as usual. To over-encapsulate the smaller capsules inside the outer capsules, the steps are the same as for outer capsule orientation except the Caps Tray is replaced with the OE Guide Tray. The number of holes must be the same during the orientation process for both the outer and inner capsules.

Batch Sizes			
The number of holes will differ by size. This does not affect the instructions for use except where noted.			
Capsule Size	Number of Outer Capsules in Filler	Number of Holes in Attachment	Number of Cycles
A, B, D	270	90	3
AA, AAel	180	90	2
AAA	120	60	2

INSERTING CAPSULES INTO OUTER CAPSULES



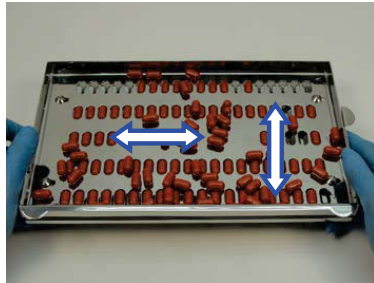
1. These instructions begin after outer capsules are oriented, separated, and seated into Filler.



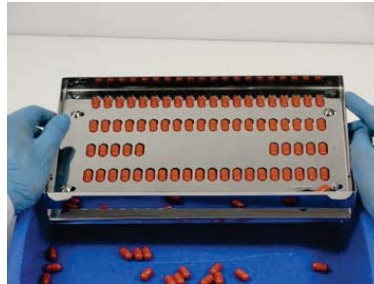
2. Place the OE Guide Tray onto the Filler Base.



3. Place the Capsule Orienter Base on the OE Guide Tray. Align the front edge of the Orienter Base with horizontal line I on OE Guide Tray. Align the right edge of the Orienter Base with the right edge of the OE Guide Tray.



4. Pour caplets onto Caplet Tray and tilt in all directions moving caplets into slots.



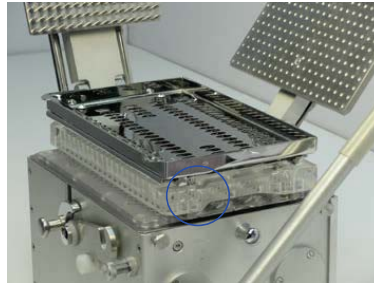
5. Tilt Caplet Tray to pour off excess caplets.



6. Place Caplet Tray on Caplet Orienter Base and slide back until it drops into place.



7. Push sliding portion of Caplet Tray to the left to drop the caplets into the capsules.



8. For all sizes, move the Caplet Orienter Base with Caplet Tray to position II on OE Guide Tray. Repeat steps 4-7.

For sizes A, B, and D only, a third cycle is required. Move the Caplet Orienter Base with Caplet Tray to position III on OE Guide Tray. Repeat steps 4-7.



9. Remove the Caplet Orienter Base, Caplet Tray and OE Guide Tray. Continue with Operating Instructions in your ProFiller 3700/3800 Manual. Begin with "Filling Capsules" if adding an excipient (page 18 in Manual v 1.2.1), or continue with "Locking Capsules" to lock the outer capsules (page 20 in v 1.2.1).

D. LOCKING CAPSULES



After inserting trial product or filling powder, follow the instructions in the ProFiller 3700/3800 Manual Operating Instructions for "Locking Capsules" (page 20 in Manual v 1.2.1).