

Hand-Held Capsule Filling System For Use in R&D • Pharmacy Compounding • Nutritional Supplements • Clinical Studies



NEW FEATURES

- All metal parts Inox (SS316)
- Fully dishwasher safe
- Includes Capsule Locker & **Powder Tray Clamps**
- Faster Orienter size change

Fill Sizes 00-4 using only Change Parts



Available in 300 hole handheld & bench-top. www.profiller.com

Easier To Use

- Multiple design features make it easier to use than other 100 hole systems (pg. 2).
- Fill powder using tapping, tamping or vibration (optional) Now 20% smaller for easier tapping.
- Includes a Capsule Locker for hard-to-lock powders.
- Shipped fully assembled. Ready for use in 5 minutes.
- Video tips at www.profiller.com. Well-illustrated manuals in multiple languages.

Faster Size Changes & Cleaning

- Change capsule sizes in only 2 minutes. Change Parts available for Size 000-5, 00el-2el.
- Size changes are adjustment and tool free.
- All parts are dishwasher safe & can be dried in a hot air • oven or with a portable hair dryer.
- Designed for fast disassembly & visual verification of cleaning.
- High GMP, all metal parts are lnox (316 stainless steel).

Pharmacopoeia Compliant

- Fill weights, USP/EP method within \pm 1-2% of average. More information at www.profiller.com/fw.
- Validation package available for cGMP compliance.
- Works with all capsules including gelatin, vegetarian/HPMC and starch capsules.

Up to 2000-3200 capsules/hour

based on powder, operator speed & number of taps/tamps.

Higher Output

- Up to 35% faster than other 100 hole systems based on a patented design and included accessories.
- Inox (Stainless Steel 316) plates for reduced static.
- Tamper size range optimized for higher fill weights and faster filling.
- Unique features include lightweight 2-piece Orienter, Orienter locater and oversize Powder Tray & clamps.
- Fully lock capsules after filling, unlike most hand-held fillers saving you time and frustration!

Optional Accessories

- Powder Vibrator.
- Partial Batch Kit for filling fewer than 100 capsules / batch.
- Capsule Handling Tray. (June 2013)
- Over-Encapsulation parts for tablets, capsules & caplets.

For filling AAA-E ask about the ProFill OE.

For Higher Output choose from our 300-hole systems







ProFiller 3600

ProFiller 3700

ProFiller 3800

Distributed By:

15 design elements that make the ProFiller 1100 the 100-hole Hand-Held Filler of Choice

Shipped Fully Assembled Fully Dishwasher Safe 2 minute Size Changeover

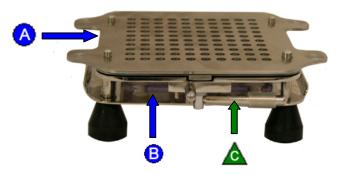
Ease of Use



GMP



Speed





All metal parts Inox (316 Stainless Steel) for less static and improved GMP



3 Body Sheets enable 100% separation of all capsule types including HMPC (vegetarian) capsules.



Adjustment-free Spacer Plate for fast size changes and consistent fill weight



Cam Handle for fast capsule separation





Locking Plate with domes to prevent capsule cap dents



Fully separates from Caps Tray for easy removal of filled capsules.



25-hole Capsule Locker is size-specific. Speeds locking, prevents over-locking & capsule body dents



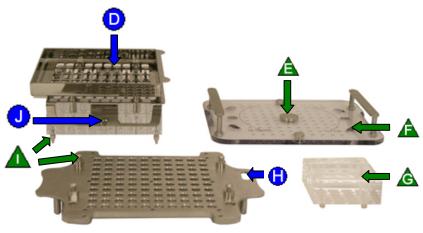
Locked Capsule Indicator



Locating Pins in Orienter & locating holes in Filler for 100% capsule transfer into Filler



Orienter. Now only 2 screws from sides for size change. Use without screws and shake only lightweight orienter tray.







Powder Tray is extra deep for fast spreading



50-pin Tamper in optimum size ranges for faster filling & higher fill weight. E.g. 00, 0-1, 2-3 & 4



Powder Tray clamps for pharmacy compounding or filling on optional Vibrator



Full size Powder Spreaders (2)



Special Fill Materials / Change Parts

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Special Fill Materials

When to use a Powder Vibrator - see www.profiller.com/vibrators

The optional Vibrator is especially helpful when filling certain materials:

- Fluffy and fine powders such as Charcoal.
- Powders that bridge such as Tyrosine or Calcium Carbonate.
- Powders that can stick to Tamper pins such as Frankincense or Dolomite.
- Granules where tamping can cause granules to break or compress such as Omeprazole.

Filling Liquids

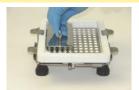
After separating capsules, leave capsules in raised position. Fill capsules with a pipette or syringe. After filling, slowly push Cam Lever back to release capsule bodies so they are level with top surface of Filler. Continue with Locking capsules.

Capsules filled with liquids for stability or clinical trials, if not sealed, must be kept vertical to minimize leakage between the cap and body. Capsules filled with liquids for commercial sale require sealing using equipment purchased separately. Capsules should be used with non-aqueous liquids only.



Filling Sticky Powders

Separate the capsules and release Cam Lever so bodies are flush with top surface of Filler. Before tamping the powder, pull Cam Lever towards you until a gentle pressure holds capsules in place. When filling sticky powder, this will prevent capsule bodies from being pulled up with Tamper after powder compression.



Over-encapsulation / Double Blinding of Tablets, Capsules and Caplets.

A full range of accessories is available (page 6).



Partial Filling Of Capsules

A custom made attachment can be ordered to partially fill 100 capsules using your existing ProFiller System e.g. for inhalation capsules. Fill weight variation is within ±7% of average. Contact us for powder specifications required to design the attachment. Delivery 6-8 weeks.



Installing Change Parts



ProFiller 1100 system's patented design requires no tools or adjustments to change capsule size.



1. Unscrew 2 thumbscrews holding Orienter Tray to Base.



2. Position new Orienter Tray and secure with 2 thumbscrews.



3. Remove Caps Tray.



4. Set Cam Lever to 3 o'clock. Remove the 3 Body Sheets.



5. Lift out clear Spacer Plate and replace with new size Spacer Plate.



6. Place new size Body Sheet "a" then "b", then "c" on locating pins.



7. Place new size Caps Tray onto Filler. You are now ready to fill a new capsule size.



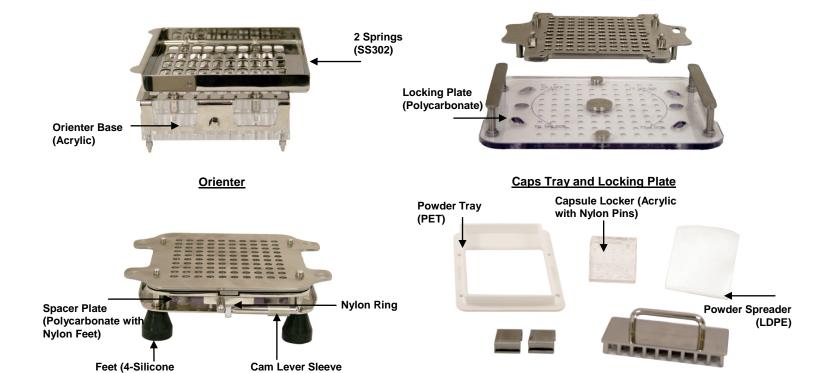
Rubber)

Materials of Construction / Cleaning

For Use in R&D • Pharmacy Compounding • Nutritional Supplements • Clinical Studies

Materials of Construction

All Parts Dishwasher Safe



<u>Filler</u> <u>Accessories</u>

Parts not otherwise labeled are made of Inox (Stainless Steel 316).

(Silicone Rubber)

Nylon parts are known to discolor when used with Erythrosine. The Powder Spreader is known to discolor when used with Beta Carotene or Sunset Yellow.

| Cleaning & Drying Methods | | | | |
|--|--|--|--|--|
| Automatic Dishwasher All parts are fully dishwasher safe using automatic dishwasher detergents. Plastic parts should be placed in top rack (<70°C / 160°F). | | | | |
| Cleaning Agents | We recommend cleaning using household hand dishwashing liquid. All items may be cleaned with NaOH (caustic soda) 1-2% solution, 1% sodium thiosulphate solution, or liquid detergents with up to 4% sodium hypochlorite. | | | |
| Isopropyl Alcohol | Wipe with a cloth dipped in isopropyl alcohol, then immediately wipe dry with a clean cloth. Do not use on Orienter Base or Capsule Locker. | | | |
| Hot Air Drying | Up to 60° C. Remove plastic parts from oven after 15-20 minutes. If using portable hair dryer, keep a distance of 12 inches (30 cm) from all items. | | | |
| Autoclave | Do not autoclave Orienter Base, Capsule Locker, Powder Spreader, Powder Tray. Other parts may be autoclaved at 121°C, 15 psi pressure for 15 minutes. | | | |

See Manual for more information on cleaning products and methods.



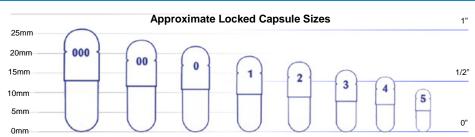


Ordering Information

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| Item Description | | | Capsule Size | | Item # | |
|---|----------------------|-------|-------------------------------|-----------|--------------------------|--|
| Full System | | | | | | |
| Everything you need to fill one capsule size: | | | 00 | | P10 HHS 00 | |
| | | | 0 | | P10 HHS 0 | |
| Hand-Held Filler Base, Orienter Base and Locking Plate | 10 0 | 1 | | P10 HHS 1 | | |
| Change Parts for one capsule size | | | 2 | | P10 HHS 2 | |
| 50-pin Tamper | ALL STREET | | 3 | | P10 HHS 3 | |
| Powder SpreaderPowder Tray | | | 4 | | P10 HHS 4 | |
| Powder Tray Clamps | | | 5 | | P10 HHS 5 | |
| Need to fill more than one Cansule size? | Sacra Contract | | 000 (80 holes) | | P10 HHS 000 | |
| Need to fill more than one Capsule size? See our combo packages below. | | | 00el - 2el & AAA-E | | Email for Price | |
| Change Parts | | | | | | |
| | | | 00 | | P10 CPS 00 | |
| Change parts for one capsule size include: | Managar (10) | | 0 | | P10 CPS 0 | |
| Caps Tray Date Office of Oct. | | | 1 | | P10 CPS 1 | |
| Body Sheet SetSpacer Plate | | | 2 | | P10 CPS 2 | |
| Capsule Locker | Tomming. | 3 | | P10 CPS 3 | | |
| Orienter Tray | | | 4 | | P10 CPS 4 | |
| Official ridy | | | 000, 00el - 2el, 5 & AAA-E | | Email for Price | |
| Tamper | | | | | | |
| 50-pin tamper | | Size | 00 | | P10 T50P 00 | |
| oo piir tampor | | Range | 0-1 & 0el-1el | | P10 T50P 0-1 | |
| | MRRRRRRRA | | 2-3 & 2el | | P10 T50P 2-3 | |
| | | | 4 | | P10 T50P 4 | |
| Powder Vibrator | | | Voltage/Frequency | | Item # | |
| Recommended for faster filling of powders that bridge or are granular, fluid or flour-like. It also | | A | 100-120 Volts/ 50-60Hz | | PM VIBHH 110 | |
| reduces weight variation of fine powders. | | | 220-240 Volts/ 50Hz | | PM VIBHH 230 | |
| Combination Packages | | | | | | |
| Combo Package A | | | 0.01 | | 50-Pin Tampers for sizes | |
| Choose 3 sizes from 00, 0, 1, 2, 3 or 4 | cludes 1 Full system | + | 2 Change Parts sets | + | ordered | |
| Combo Package B | cludes 1 Full system | + | 3 Change Parts sets | + | 50-Pin Tampers for sizes | |
| Choose 4 sizes from 00, 0, 1, 2, 3 or 4. | Full System | + | 5 Change Falls sels | + | ordered | |

Capsule Size Chart







Accessories / Weights & Dimensions For Use in R&D • Pharmacy Compounding • Nutritional Supplements • Clinical Studies

| Item Description | | Capsule Size | Item # |
|--|--|---------------------------------------|---|
| | Optional Accessories | | |
| Maintenance Kit Includes 1 cleaning brush, 1 nylon cleaning pad, 2 Filler Base feet, 2 Orienter Base screws, & 2 Spacer Plate feet for each size. | Pour IV Marinema va KO kry Judes. Interference For Ko kry Judes. Interference Interferen | 00-4 | P1X MK 00-4 |
| Partial Batch Kit Fill fewer than 100 capsules per batch. Includes 1 each of Orienter Divider, Powder Tray Divider & 5-pin Tamper. | | 00-4 & 0el-2el | P1X PBK 00-4 |
| Tamper 5-Pin Each side of the Tamper is for a different capsules size range. | 三星 | 00-1 & 2-4 (including el sizes) | P1X T5P 00-4 |
| Filler Change Parts Continue production with a fresh set of Filler Change Parts while another set is being washed & dried | | 00, 0, 1, 2, 3 or 4 | P10 FCP CS* *CS = capsule size. |
| Tap Densimeter Used to determine tapped density for capsule filling. Eliminates calculation errors as volume is 1 ml. | Parking | n/a | PXX-TDM |
| Capsule Handling Tray Use to transfer filled capsules from Caps Tray into a large mouth bottle or other container. | 1 | n/a | P1X-CHT Available June 2013 |
| Tamper 100-Pin For Faster Filling | Lananan attenti | 00 0-1 & 0el-1el 2-3 & 2el 4 | P10 T100P 00 P10 T100P 0-1 P10 T100P 2-3 P10 T100P 4 |
| Bottom Plate Adjustable Lowering capsule bodies by 2 mm increases fill weight by 10-15% for many powders and 2-4% for coarse or granulated powders that do not compress. | | 00-4 | P10 BPA 00-4 |

Over-Encapsulation Accessories (Email for Prices)









| Orienter For Capsule in Capsule | |
|---------------------------------|--|
| P10 NEC OCPOB 1 & 2 | |

Tablet Fill Attachment (Standard) P10 TFA STD 00-0 3

Tablet Fill Attachment (Custom) Dimension of Tablet required.

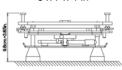
Caplet Attachment (Custom) Dimension of Caplet required.

¹ Specify Capsule Size when ordering.

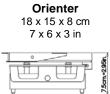
² Order Guide Tray P10 OEG separately - ³ For round tablets 6.1-9.0 mm diameter & 2.0-5.0 mm height.

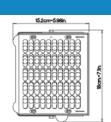
Shipping Weight and Dimensions (Approximate)

Filler 21 x 19 x 10 cm 8 x 7 x 4 in









| Item | Boxes | Shipping Wt. | | Net Wt. | |
|--------------------------------------|---------|--------------|-----|---------|-----|
| item | | kg | lbs | kg | lbs |
| Complete System for one Capsule Size | Box 1/1 | 6.5 | 14 | 4.8 | 11 |
| Extra Change Parts | Box 1/1 | 3.5 | 8 | 2.3 | 5 |
| Extra Tamper | Box 1/1 | 0.5 | 1 | 0.3 | 0.7 |
| Extra Orienter Base | Box 1/1 | 1.0 | 2 | 0.5 | 1 |
| Vibrator (optional) | Box 1/1 | 8.0 | 18 | 6.5 | 15 |



Frequently Asked Questions

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1. What is the output?

Output is 2000 - 3200 capsules per hour. Our engineers have designed over 15 features that make the ProFiller 1100 the **fastest** and **easiest** 100-hole hand-held filling system on the market. The lower output is for fine powders. The higher output is for coarse free-flowing powders. Your results will vary based on the powder flow properties, operator speed & technique and use of excipients.

2. How accurate are fill weights?

Fill weights using the USP/EP method are within \pm 1-2% of target. When weighed individually (a stricter standard than USP/EP), typically all 100 capsules/batch are within \pm 4-7.5% of target. For more information visit www.profiller.com/fw.

3. What types of capsules can I fill?

We have successfully tested different brands and types of capsules including gelatin, HPMC (vegetarian) and pullulan (starch) capsules. Our 3 Body Sheet Set design enables 100% separation of vegetarian capsules.

4. What size capsules can I fill?

Standard sizes 00, 0, 1, 2, 3, 4, 5 and both European & USA 0el, 1el & 2el (100 hole); 000 and 00el (80 hole). Change Parts for standard sizes can be ordered to fill additional sizes on the same system. ProFiller OE is available for sizes AAA, AAel, AA, A, B & D. AAA-E sizes require a separate system for each size.

5. How big is the system and how can I store it?

The largest piece is the Filler, which measures approximately 8 x 7 x 4 inches or 21 x 19 x 10 cm. The entire system can comfortably fit in a regular office desk drawer.

6. Can I over-encapsulate or double-blind tablets, capsules and caplets?

Yes, you can. See page 6 for more information and special attachments.

7. Can I fill liquids or sticky powders?

The ProFiller system can be used to fill capsules with non-aqueous liquids or sticky powders. See Page 3 for tips, or visit www.profiller.com/tips and follow the link for special fill materials.

8. Can the ProFiller 1100 be cleaned in an automatic dishwasher?

Yes, the entire system can be placed in an automatic dishwasher and is safe for use with automatic dishwasher detergents.

9. What is the ProFiller system made of?

See page 4 for the materials of construction.

10. What is the shipping weight and size?

| | English | Metric | | |
|-----------------|----------------|-----------------|--|--|
| Shipping Weight | 14 lbs | 6.5 kg | | |
| Shipping Size | 18 x 11 x 7 in | 45 x 28 x 17 cm | | |

11. Is there a larger ProFiller available?

Yes, the ProFiller 3600, 3700 & 3800 fill 300 capsules per cycle and have an output of up to 3-4X that of the ProFiller 1100. Visit www.profiller.com.

12. What are the maintenance requirements?

We recommend daily cleaning, preferably washing, of the machine to remove any powder. At a minimum the cam and the cam bush on the underside of sheet "b" should be wiped clean of powder and lubricated with a food grade lubricant (e.g. Vaseline petroleum jelly).

13. Why Might I Need an Additional Orienter Base or Capsule Locking Plate?

The Orienter Base (HOB) is in three capsule size rages: 00-4, 5 and 000/00el. The Capsule Locking Plate (CLP) is in two size ranges 00-5 (100 hole) and 000/00el (80 hole). To fill capsule sizes outside the size range of what you received with your full system, you need to purchase the additional item(s).

14. What fill materials are known to discolor the ProFiller 1100?

Most fill materials will not discolor the ProFiller. See the Materials of Construction on page 4 for a list of materials known to discolor one or more parts of the ProFiller. If you have questions on a specific fill material contact us via www.profiller.com.

15. Is a CE certificate Available?

A "Declaration of Conformity" is included with each system. A CE certificate is included with the optional Vibrator.

If you have additional questions that are not answered here, or you would like additional information, please visit www.profiller.com. The website contains detailed information about using, cleaning, and caring for your ProFiller System

ProFiller Products

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Capsule Filling Equipment



Handheld 100-hole Capsule Filler for AAA-D

Up to 1000-1500 doses/hour. Available in 100 holes for sizes AAel, AA, A, B, D; and in 64 holes for AAA. Tablets that fit in C & E also fit in the next larger size capsule i.e. B & D.





Handheld 300-hole Capsule Filler

For the growing company and for use under powder hoods or in glove-box isolators. Fully locks capsules after filling. The only 300-hole hand-held you can upgrade as the Change Parts of the 3600 also fit the 3700 bench-top Filler. The same Orienter works with 3600 & 3700. Output up to 4500-6900 Capsules per hour. Available in Sizes 000-4 & all el sizes.





Bench-top* Capsule Filler & Hand-held Orienter

Easiest bench-top system to set-up and use. Includes a hand-held Orienter. Up to 6000-9000 capsules per hour. Options include Partial Batch Kit and Vibrator. Available in Sizes 000-5, all el sizes & for AAA-D.





Bench-top* Capsule Filler & European Style Orienter

Our bench-top system for those who prefer the traditional European style semi-automatic Orienter. Up to 6000-9000 capsules per hour. Optional Vibrator. Available in Sizes 00-4. Other sizes use a handheld orienter.



*Bench-top Systems are designed for easier operation to enable continuous production. The 3700 includes our innovative hand-held orienter. For customers who use the traditional European style "semi-automatic" orienter we offer the 3800.

Other Equipment



Capsule / Caplet Film Coater

For R&D. Ideal for enteric or film coating small batches of capsules and caplets with solvent based coatings. For capsules sizes 00-3.





Filling Funnels

For precision capsule filling on a balance. Includes Tamper. Made from Inox (316 stainless steel). Available in all capsule sizes including veterinary sizes.



Powder Mixer (V-Blender)



ProMixer (Powder Blender)

For consistent, gentle and uniform mixing of powders in 5-10 minutes. Shells available in "V" or Drum shape in sizes for 60, 100/120 and 300 capsules/batch. Shells are in Inox (SS316) for smoother powder flow & easy cleaning.

