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

ProFiller^{® 1100}

- 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

- ٠ 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 Inox (316 stainless steel). •

Pharmacopoeia Compliant

- * Fill weights, USP/EP method within \pm 1-2% of average. More information at www.profiller.com/fw.
- ٠ 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 DBcaps[®] ask about the ProFill OE.

For Higher Output choose from our 300-hole systems



Designed and Manufactured by:



www.torpac.com info37@torpac.com T: 1-973-244-1125 F: 1-973-244-1365 333 Route 46, Fairfield, NJ 07004, USA ProFiller[®] 1100

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

Shipped Fully Assembled Ease of Use **Fully Dishwasher Safe** GMP 2 minute Size Changeover 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 в changes and consistent fill weight Cam Handle for fast capsule separation C Patented design slots, laser cut for 100% D capsule orientation 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 & G 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. ĸ 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 ANNANA I N

Full size Powder Spreaders (2)



Special Fill Materials

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

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 $\pm 7\%$ 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.



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



1. Unscrew 2 thumbscrews holding

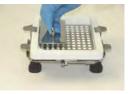
Orienter Tray to Base.

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.











3. Remove Caps Tray.



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

Materials of Construction

All Parts Dishwasher Safe



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

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

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

Item Description Full System

Everything you need to fill one capsule size:

- Hand-Held Filler Base, Orienter Base
 and Locking Plate
- Change Parts for one capsule size

oFiller

- 50-pin Tamper
- Powder Spreader
- Powder Tray
- Powder Tray Clamps

Need to fill more than one Capsule size? See our combo packages below.



Capsule Size	Item #	Regular	5% Intro
			Discount
00	P10 HHS 00	\$1080.00	\$1026.00
0	P10 HHS 0	\$1080.00	\$1026.00
1	P10 HHS 1	\$1080.00	\$1026.00
2	P10 HHS 2	\$1080.00	\$1026.00
3	P10 HHS 3	\$1080.00	\$1026.00
4	P10 HHS 4	\$1080.00	\$1026.00
5	P10 HHS 5	\$1230.00	-
000 (80 holes)	P10 HHS 000	\$1230.00	-
00el - 2el & AAA-E	Email fo	r Price	-

Change Parts

Change parts for one capsule size include:

- Caps Tray
- Body Sheet Set
- Spacer Plate
- Capsule Locker
- Orienter Tray

Tamper

50-pin tamper

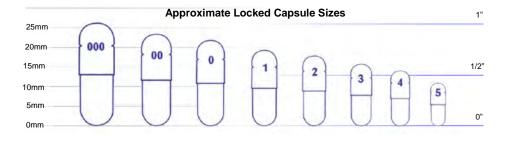


	00	P10 CPS 00	\$610.00	\$579.50
	0	P10 CPS 0	\$610.00	\$579.50
	1	P10 CPS 1	\$610.00	\$579.50
0	2	P10 CPS 2	\$610.00	\$579.50
8	3	P10 CPS 3	\$610.00	\$579.50
	4	P10 CPS 4	\$610.00	\$579.50
	000, 00el - 2el, 5 & AAA-E	Email for	r Price	-

c	Size	00	P10 T50P 00	\$90.00	-
	Range	0-1 & 0el-1el	P10 T50P 0-1	\$90.00	-
NERRAR AND		2-3 & 2el	P10 T50P 2-3	\$90.00	-
		4	P10 T50P 4	\$90.00	-

Powder Vibrator					Voltage/	Frequ	uency Ite	em #		
Recommended for faster filling of powders that bridge or are granular, fluid or flour-like. It also reduces weight variation of fine powders.				100-120 Volts/ 50-60Hz 220-240 Volts/ 50Hz			VIBHH 10	\$455.00	-	
							VIBHH 230	\$455.00	-	
Combination Packages										
Combo Package A	Includes	1 Full system		2 Change	e Parts sets		50-Pin Tamp	pers for	\$2300.00	\$2185.00
Choose 3 sizes from 00, 0, 1, 2, 3 or 4	includes	i Fuil System	+	2 Change	Fails Sels	+	sizes orde	ered	φ 2 300.00	φ2165.00
Combo Package B	Includes	1 Full over		2 Change			50-Pin Tamp	pers for	¢2200.00	¢0745.00
Choose 4 sizes from 00, 0, 1, 2, 3 or 4.	Includes	1 Full system	+	3 Change	Parts sets	+	sizes orde	ered	\$2890.00	\$2745.00

Capsule Size Chart





ProFiller^{® 1100}

Accessories / Weights & Dimensions

Item Description	Ontion	al Accessories	Capsule Size	Item #	US\$
Maintenance Kit Includes 1 cleaning brush, 1 nylon cleaning Base feet, 2 Orienter Base screws, & 2 Sp each size.	g pad, 2 Filler	ACCESSORES	00-4	P1X MK 00-4	\$45.00
Partial Batch Kit Fill fewer than 100 capsules per batch. Inc Orienter Divider, Powder Tray Divider & 5-		· ····································	00-4 & 0el-2el	P1X PBK 00-4	\$90.0
Tamper 5-Pin Each side of the Tamper is for a different c range.	apsules size	THE A	00-1 & 2-4 (including el sizes)	P1X T5P 00-4	\$16.5
Filler Change Parts Continue production with a fresh set of Fille while another set is being washed & dried	er Change Parts		00, 0, 1, 2, 3 or 4	P10 FCP CS* *CS = capsule size.	\$440.0
Tap DensimeterUsed to determine tapped density for capsEliminates calculation errors as volume is		President	n/a	PXX-TDM	\$25.0
Capsule Handling Tray Use to transfer filled capsules from Caps T mouth bottle or other container.	ray into a large		n/a	P1X-CHT	Available June 2013
Tamper 100-Pin For Faster Filling		Caranana service	00 0-1 & 0el-1el 2-3 & 2el 4	P10 T100P 00 P10 T100P 0-1 P10 T100P 2-3 P10 T100P 4	\$165.00
Bottom Plate Adjustable Lowering capsule bodies by 2 mm increase 10-15% for many powders and 2-4% for co granulated powders that do not compress.	es fill weight by parse or		00-4	P10 BPA 00-4	\$95.0
	Over-Encapsulation A	ccessories (Ema	il for Prices)		
		A THE			
Orienter For Capsule in Capsule Ta	blet Fill Attachment (Standar	d) Tablet Fill At	tachment (Custom)	Caplet Attachment (Custom)
P10 NEC OCPOB ^{1 & 2}	P10 TFA STD 00-0 ³		of Tablet required.	Dimension of Caplet	•
¹ Specify Capsule Size when ordering.	² Order Guide Tray P10 OE			mm diameter & 2.0-5.0	mm height.
	Shipping Weight and	Dimensions (Ap		15.2cm-5.98in	<u> </u>
Filler 21 x 19 x 10 cm 8 x 7 x 4 in			Orienter 18 x 15 x 8 cm 7 x 6 x 3 in		1990 1990 1990 1990 1990 1990 1990 1990
Item	Boxes	s SI kg	hipping Wt. Ibs	Net Wt. kg	lbs
Complete System for one Capsule Size Extra Change Parts	Box 1/ Box 1/	1 6.5	14	4.8	11
Extra Tamper	Box 1/	1 0.5	8 1	2.3 0.3	5 0.7
Extra Orienter Base Vibrator (optional)	Box 1/ Box 1/		2 18	0.5 6.5	1 15

ProFiller 1100 Brochure 1302

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 <u>www.profiller.com/tips</u> 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 <u>www.profiller.com</u>.

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 <u>www.profiller.com</u>.

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 <u>www.profiller.com</u>. The website contains detailed information about using, cleaning, and caring for your ProFiller System

ProFiller¹¹⁹⁹

Capsule Filling Equipment



Handheld 100-hole Capsule Filler for DBcaps[®]

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 glovebox 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 DBcaps[®].





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.



ProFim



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.





ProFiller 1100 Brochure 1302

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