

Gri-fill® is a closed system which allows sterile solutions to be prepared in different volumes, contents and proportions than those produced by the pharmaceutical industry, all without the need for laminar flow hoods. The **Gri-fill® 3.0** System can be placed inside a standard laminar airflow hood or biosafety cabinet when extra protection is desired (ie with antineoplastics). The **Gri-fill®** System maintains sterility via the principle of sterile filtration and quality control when Gri-bags™ and Gri-flex™ final containers are used. Each unit prepared undergoes final filtration through a 0.22 micron filter and its integrity is automatically verified.



- 1 Rear panel with on/off switch and external communication ports
- 2 Source solution 1 (drug or diluent)
- 3 Source solution 2 (drug or diluent)
- 4 Key pad to access up to 40 stored drug combinations or to create a new combination
- 5 Protective door. When opened prevents the system from working, when closed prevents access to the system
- 6 Flow distributor to control the process (withdrawal of source solution, delivery to final container, entry of air, etc.)
- 7 Load cell to measure pressures
- 8 Disposable, sterile set with standard pre-attached 60mL syringe
- 9 Intake air filter
- 10 Gri-bag™ with 0.22 micron filter attached
- 11 Container for excess air and fluid from priming (not visible)



Added Process Control for Oncology

- While the incidence of documented chemotherapy medication errors vary, the outcome of an error can be more serious with up to 25% of chemotherapy errors resulting in deaths¹
- Common sources of error cited have been non-computerized orders, omission of information and increased workload²
- Systematic Process Control is critical in preventing errors

The **Gri-fill®** System simplifies implementation of standard processes/protocols through storage of 40 specific combinations to maximize control.

Protection

- Filtration of every dose in the pharmacy minimizes the risk of inadvertent contamination during compounding and gives the pharmacy confidence to assign dating based on chemical stability of the medication
- Preparing parenteral admixtures in the pharmacy avoids future handling, reducing the potential for medication errors and the incidence of nosocomial illnesses³

USP <797>

- Calls for high quality assurance standards
- Calls for limits on expiration date assignment (“beyond use dating”) without stringent sterility assurance controls

The **Gri-fill®** System maintains sterility of compounded sterile products and documents the quality control unit by unit (integrity test of filter at the end of each dose) when Gri-bag™ or Gri-flex™ containers are used.

Distributed in USA by:

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Traceability

- After compounding with the **Gri-fill®** System, each bag remains sealed, sterile, identified, and ready to administer
- Documentation of drug, dose, diluent, lot number, expiration date, time of preparation and preparer can all be archived by the user in an electronic file

Risk Management

- Minimizes the risk of inadvertent contamination during compounding
- Avoids the risk of repetitive stress injuries from pulling back and pushing on syringe plungers
- Minimizes the risk of medication error with a systematic process

Applications

- **Gri-fill®** permits the compounding and mixing of any liquid medication
- Permits compounding from 2 different source solutions in small batch preparations or patient-specific preparations
- Ability to customize settings to adjust for differences in viscosity and potential for foaming during compounding
- Can be linked with up to 7 additional compounders to maximize efficiency
- Reconstitution mode allows for customized reconstitution and filling with the same set

Please refer to user manual for detailed information about the safe and appropriate use of the **Gri-fill®** System 3.0.

Order No.	Description
GFL3.0	Gri-fill® 3.0 Compounder

¹Misadventures in Cancer Care, Seminars in Oncology Nursing, 2002; Chemotherapy Medication Errors: Descriptions, Severity and Contribution Factors, 1999

²Farm Hosp 2003 Jul-Aug; 27(4):219-23; Pharm World Sci 2001 Jun; 2:102-6; Am J Health Syst Pharm 2000 Dec 15; 57 (Suppl 4)

³Flynn EA, Pearson RE, Barker KN. Observational study of accuracy in compounding IV admixtures at five hospitals. Am J Health Syst Pharm 1997; 54: 904-12