

Instructions for Use (IFU)

Green Drain™ — Waterless Drain Trap Seal

1. Device Identification

Product Name: Green Drain™

Device Type: Passive mechanical drain trap seal

Variants: GD1.25 – GD6 (various sizes)

Manufacturer:

Green Drain Europe ApS

Birk Centerpark 40

DK-7400 Herning

Denmark

Single Registration Number (SRN): DK-MF-000052289

2. Intended Purpose

Green Drain™ is a non-invasive, passive device intended for installation in floor drain systems within built environments, including healthcare facilities.

The device functions as a mechanical barrier to reduce environmental exposure to air and aerosolised particles originating from drain systems, under defined conditions of use.

Green Drain™ is intended to support hygiene management and infection prevention and control measures by limiting drain-mediated exposure pathways.

The device does not act on the human body and does not achieve its purpose by pharmacological, immunological, or metabolic means.

3. Intended Users and Environment

Intended Users:

Installation and maintenance must be performed by trained personnel, such as facility staff or technical service providers.

Environment of Use:

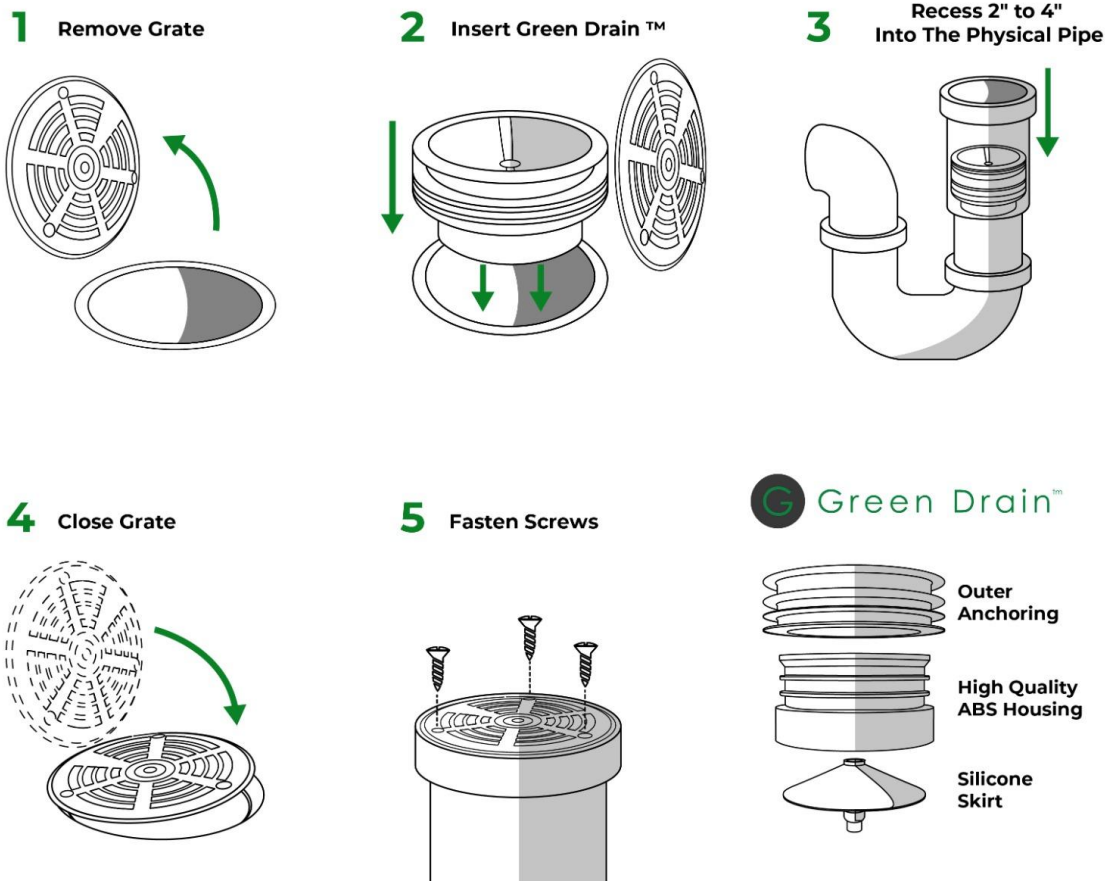
- hospitals
- clinics
- outpatient facilities
- long-term care facilities
- other built environments with floor drain systems

4. Installation Instructions

Follow the steps below:

1. Remove existing drain grate
2. Insert Green Drain™ into the drain opening
3. Position the device within the pipe as appropriate for the drain configuration
4. Replace and close the drain grate
5. Secure using screws if applicable

Ensure the device is correctly seated and stable within the drain system.



5. Warnings and Limitations

- Green Drain™ is a passive environmental control device and does not prevent, diagnose, treat, or cure disease.
- The device does not replace established hygiene protocols, cleaning procedures, or infection prevention measures.
- No claims are made regarding reduction of infection rates or patient outcomes.
- Performance depends on correct installation and appropriate use within a broader hygiene management framework.
- The device is not intended for direct interaction with patients.

6. Use and Handling

- The device operates automatically once installed
- No active user interaction is required during normal operation
- Ensure the device remains properly positioned within the drain

7. Maintenance and Inspection

- Periodically inspect for correct positioning and integrity
- Remove and reinstall if displacement is observed
- Replace the device if visible damage or degradation occurs

8. Removal

To remove the device:

1. Remove the drain grate
2. Extract the device from the drain
3. Inspect and clean or replace as necessary

9. Disposal

- Dispose of the device in accordance with local regulations
- If contamination (e.g. biofilm or hazardous substances) is suspected, handle and dispose of as potentially contaminated waste

10. Materials

- Housing: ABS polymer
- Membrane: silicone-based elastomer

No information indicating the presence of natural rubber latex is identified in available material specifications.

11. Storage

- Store in a clean, dry environment
- Avoid exposure to extreme temperatures or mechanical stress prior to installation

12. Traceability

Each device or packaging unit includes identification allowing traceability (e.g. batch or lot number).

Variant	UDI-DI
Basic	5745001471GreenDrainMDRJD
GD125	05745001471002
GD15	05745001471019
GD2	05745001471026
GD3	05745001471033
GD35	05745001471040
GD4	05745001471057
GD5	05745001471064
GD6	05745001471071

13. Date of Issue

20 April 2026

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