



Instructions for Use

Benco Dental™ Unidose Composite Gun

1: Intended Purpose

The Unidose Composite Carpule Gun is a reusable, hand-held dispensing device designed to deliver single-dose composite resin (in pre-filled 0.25–0.35 g carpules) directly into a prepared tooth cavity.

2: Indications for Use

- Dispensing light-curable or self-curing restorative composites supplied in compatible unidose carpules.
- Chairside use by licensed dental professionals only.

3: Contraindications

- Do not use with bulk syringes, flowable composites, or materials not packaged in manufacturer-approved unidose carpules.
- Contraindicated for intraoral heating or solvent cleaning.

4: Device Description

Component	Material	Sterilizable
Trigger Handle	Anodized aluminum	Yes
Push Rod & Plunger	Stainless steel	Yes
Carpule Holder	High-density polymer	Yes
Return Spring	Stainless steel	Yes

5: Before First Use

1. Remove all packaging.
2. Disassemble per Section 9.
3. Clean and steam-sterilize (see Section 10).
4. Inspect surfaces; discard if cracked, bent, or corroded.

6: Operating Instructions

1. Load

- Retract the push rod fully by squeezing the trigger twice without a carpule.
- Insert a new unidose carpule into the holder until it seats firmly.
- Release trigger; the plunger should contact the carpule piston lightly.

2. Dispense

- Position the cannula tip at the cavity floor.
- Squeeze trigger gently; composite extrudes in a controlled, incremental dose.
- Repeat as needed; do not exceed the carpule's intended volume.

3. Eject Carpule

- Fully retract push rod.
- Pull empty carpule straight out; discard as regulated medical waste.

7: Precautions & Warnings

- **Sterility:** Device is supplied non-sterile. Steam-sterilize before each patient.
- **Cross-infection:** Do not reuse carpules; single patient use only.
- **Excess Force:** Avoid excessive trigger pressure—may fracture cannula or tooth structure.
- **Chemical Exposure:** Do not expose gun components to phenols, chlorine, or solvents that degrade polymers/metals.

8: Disassembly for Reprocessing

1. Rotate carpule holder 90° counter-clockwise and pull to release.
2. Slide push rod out through rear slot.
3. Separate plunger tip from rod by unscrewing ½ turn (if applicable).
4. Remove return spring only if visibly soiled.

9: Cleaning & Sterilization

Step	Method	Parameters
Pre-Clean	Rinse under warm (≤ 40 °C) running water <2 min	Soft brush; neutral pH detergent
Ultrasonic	5 min in enzymatic bath	45–50 kHz
Rinse	Deionized water, 30 s	—
Dry	Lint-free wipe + forced air <60 °C	—
Inspect	Magnification 3–5×	No debris, cracks
Package	Sterilization pouch – Class 1 indicator	Seal per IFU
Autoclave	132–134 °C, 3–4 bar, 4 min exposure, 15 min dry	Fractionated vacuum or prevac

Note: Validate your clinic’s process in accordance with ISO 17664.

10: Storage & Handling

- Store cleaned, dry device in a covered tray at 10–30 °C, <70 % RH.
- Avoid direct UV light or chemical fumes.

11: Service Life

- Rated for 1,000 sterilization cycles. Replace earlier if function is impaired.

12: Troubleshooting Guide

Issue	Cause	Remedy
Composite leaks around carpule	Carpule mis-seated	Reload; check holder wear
No extrusion	Push rod not engaged	Retract & re-advance rod
Trigger binds	Debris in hinge	Clean & lubricate with medical-grade silicone

13: Adverse Event Reporting

Report serious incidents to the manufacturer and local competent authority per MDR 2017/745 Article 87.

14: Distributor

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