

[54] **PRODUCT AND PROCESS FOR MAKING
IMPROVED STRENGTH DENTAL
AMALGAM**

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[22] Filed: **June 20, 1972**
[21] Appl. No.: **264,619**

[52] U.S. Cl. **206/219**
[51] Int. Cl. **B65d 81/32, B65d 81/20**
[58] Field of Search 206/47 A, 46 PV, 84;
53/22, 112 R, 112 A; 75/173 A, 175

[56] **References Cited**

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& Klose

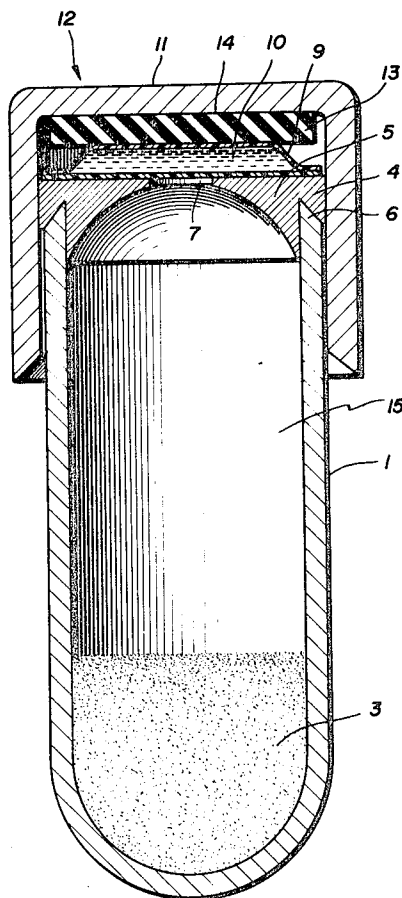
[57] **ABSTRACT**

A closed container having therein a mass of a particulate alloy containing silver and tin for use in making dental amalgam, and an inert atmosphere in the container.

The container can be an enclosed capsule in which the liquid mercury is in a separate enclosed rupturable chamber inside of the capsule which keeps the mercury out of contact with the alloy until the chamber is ruptured.

A method of making a dental amalgam by combining mercury and a particulate dental alloy, used in making dental amalgam, in an inert atmosphere.

7 Claims, 1 Drawing Figure



PRODUCT AND PROCESS FOR MAKING IMPROVED STRENGTH DENTAL AMALGAM

This invention relates to metal alloys. More particularly, this invention is concerned with improvements in dental amalgams for teeth fillings.

In filling a tooth cavity with a so-called silver filling, the dentist uses an amalgam formed by combining liquid mercury with a powdered or granular alloy. The alloy is largely silver and tin. To meet the standards of the American Dental Association ("American Dental Association Specification No. 1 for alloy for dental amalgam," pages 132-135 of Guide to Dental Materials and Devices, 5th Ed., 1970-1971; published by the American Dental Association.) the alloy must be at least 65 percent silver and must not contain more than 29 percent tin, 6 percent copper, 2 percent zinc and 3 percent mercury. The amalgam is prepared by combining about equal amounts by weight of liquid mercury and powdered alloy.

Dental amalgam fillings are comparatively easy and fast to install in teeth and perform fairly well. Amalgam fillings, however, are quite brittle and have a high incidence of fracture or splitting. About 25 percent of the dental amalgam fillings can be expected to fail and have to be replaced. Since 112 million Americans have an average of 5.5 amalgam fillings, the total number of failures is large.

An examination of failed amalgam fillings has established that failure is due not only to compressive forces but also to tensile forces. While the compressive strength of dental amalgam is quite high, the tensile strength is only about one-tenth to one-sixth of the compressive strength. The low tensile strength renders the amalgam inadequate to withstand many of the tensile forces applied to fillings. Accordingly, if the tensile strength of the amalgam can be increased, stronger fillings with less likelihood of failure can be made.

Young and Johnson, in the Journal of Dental Research, 46, 457 (1967) report mixing high purity tin and mercury, sealing the mixture into an evacuated quartz tube and heating the mixture to 300°C. They report increased tensile strength as the mercury goes from 0 to 10 percent and decreased tensile strength going from 10 to 20 percent mercury. They conclude that the way to improve the tensile strength of amalgam may be in reducing the amount of the tin-mercury phase present.

When particulate dental alloy is manufactured, it acquires an oxide coating which is believed to lower the tensile strength of amalgam made from it. However, the presence of the oxide coating slows the formation of a hard amalgam enough to give the dentist time to prepare it and fill a tooth while the amalgam is still plastic. While use of an alloy free of an oxide coating will give an amalgam of increased tensile strength, the dentist would find great difficulty in using it before it hardened.

According to the present invention, the tensile strength of a dental amalgam can be significantly increased by mixing the powdered alloy and mercury in an inert atmosphere, such as an atmosphere of argon, helium or neon or a mixture of such gases, to form the amalgam. With respect to this invention, an inert gas is defined as any gas that does not chemically react with either the dental amalgam alloy or mercury either in bulk or in a surface reaction under conditions of nor-

mal ambient temperatures and pressures in the absence of applied electrical and magnetic fields. Although the reason for the increased tensile strength of the amalgam is not fully understood, it is believed that the absence of oxygen, and perhaps also water vapor during the mixing of the alloy and mercury leads largely to the increased tensile strength. The inert atmosphere does not have an adverse effect on other qualities of the alloy, mercury or resulting amalgam.

In producing an amalgam of increased strength according to the invention, the dentist does not require special equipment or tools or new techniques. He need only form the amalgam from a powdered alloy which is bathed in an inert atmosphere when the mercury is mixed with it.

The filling materials used by a dentist in forming an amalgam are marketed in both bulk form and in capsule dosage form. The invention is useful in both forms to produce amalgam of increased tensile strength.

Dental supply manufacturing concerns market in bulk mercury and the powdered alloy used in dental amalgam. Many dentists purchase such bulk materials and use them in measured amounts as needed to make a filling. Those dentists can readily adapt the invention to continued use of such bulk materials. The dentist need only evacuate a capsule or other container, fill it with an inert gas and then add and mix the powdered alloy and mercury. After mixing, the amalgam is ready for insertion in a tooth.

To facilitate use of bulk powdered alloy by the dentist, the alloy can be marketed in small glass bottles or cans containing an inert gas. The container and alloy can be purged of air, as by a vacuum, and the alloy packaged in the container in an inert atmosphere supplied by argon, helium or neon. After the container is opened the inert atmosphere is likely to be replaced with air unless precautions are taken. Therefore, if the alloy is not all to be used within a short time, it is advisable for the opened container to be stored in a bath of inert gas. A storage box equipped with a fast opening cover and means to flood it with an inert gas can be used by the dentist for this purpose.

The capsule form in which the dental amalgam ingredients are also supplied to dentists lends itself more suitably to practice of the invention than the bulk form of material. This is because the capsules are sized to provide only enough amalgam for the fillings in progress.

Capsules of dental amalgam filling materials come in various constructions but they all apparently include a small container in the form of a capsule which holds a powdered alloy filling dosage and a rupturable chamber holding liquid mercury. The ingredients are pre-measured (commonly designated as "predosed" in dental literature) so that when totally mixed together an amalgam is obtained with the right proportion of each ingredient. The amount of liquid mercury in the capsule is generally about equal in weight to the amount of alloy. By suitable means, such as pressing or screwing down a cap or cover, or puncturing the mercury-containing chamber in some other way such as with a pin, the mercury is released to flow into admixture with the powdered alloy without opening the capsule. The capsule is then generally placed in a shaking or mixing machine to complete the mixing. After thorough mixing is obtained, the amalgam is removed from the capsule ready for compaction in a tooth cavity. U.S.

Pat. Nos. 3,655,035; 3,655,037; 3,425,598 and 3,415,360 illustrate capsules which can be used for dental amalgam materials.

Referring now to the drawing showing a capsule, reference numeral 1 denotes a cylindrical container closed at its bottom and open at its opposite end. Said cylindrical container 1, which is of circular cross-section, serves for receiving an alloy powder 3. A circular flange 4 of circular plug 5 rests on the circular upper edge 6 of cylindrical container 1 and said plug has in its center an opening 7. The upper surface of plug 5 has a slight incline from its periphery toward its central opening 7. The edge of the open upper end of cylindrical container 1 is slightly inwardly beveled at 6 to provide a satisfactory seat for plug 5. On the upper surface of plug 5 a sealed cushion-like plastic pouch 9, filled with mercury 10, is placed between plug 5 and top 11 of cap 12, which telescopically engages the outer cylindrical surface of member 1. If desired, a disc 13 of rubber or a similar material may be placed between the upper surface of pouch 9 and the inner surface 14 of top 11. The inside 15 of container 1 is filled with an inert gas. Upon pressing cap 12 downward in the drawing, pouch 9 is ruptured and from the pouch the mercury 10 flows through opening 7 into container 1, which contains the alloy powder 3. Said rubber disc 13 facilitates complete emptying of the pouch 9, upon applying pressure to cap 12.

Filling of capsules containing the alloy powder and liquid mercury with an inert gas can be effected in a number of ways. One procedure is to first place the alloy powder in an open capsule. The capsule can then be placed in a conventional dry box together with the capsule cap containing the chamber or pouch of mercury and the dry box then pumped to a high vacuum. The dry box then can be flooded with an inert gas. This will also cause each capsule to fill with the inert gas. The cap containing the mercury can then be placed on the capsule. Such manipulations can be achieved by hand operations through glove-filled ports in the dry box after it is filled with the inert gas. Once the capsules are capped, the dry box can be opened and the capsules removed. The capsules can then be distributed to dentists for use by them in making amalgam fillings.

The inert gas-filled capsules are employed by mixing the mercury and powdered alloy together before the capsule is opened. After the amalgam is produced the capsule is opened, the amalgam is removed and is placed in the cavity to be filled using conventional procedures.

The following examples are presented to further illustrate the invention.

EXAMPLE 1

10 amalgam test specimens were prepared according to the procedures on pages 132 to 135 of the "Guide to Dental Materials and Devices," referred to supra. Capsules containing premeasured about equal amounts by weight of mercury and alloy (commercially available as Amalcap 2, H. D. Justi Co.) were used. The product is included in the 1970-71 List of Certified Dental Materials of the American Dental Society. The alloy analyzed 72 wt percent silver, 26.8 wt percent tin, 2.05 wt percent mercury, 263 ppm copper and 7.65 ppm zinc. Each specimen was prepared from the contents of a single capsule. The caps were removed from the capsules and the caps containing the mercury

pouch as well as the capsule body containing the powdered alloy were placed in a dry box. Air was removed from the capsules and alloy powder by evacuation of the dry box. The dry box was then filled with argon. While still in the argon atmosphere in the dry box, the caps were then placed on the capsules and the assembled capsules were then removed from the dry box. The mercury and powdered alloy were mixed together (trituated) in the argon atmosphere, for 5.5 seconds, using a mechanical (Silamat) amalgamator oscillating at approximately 4,570 rpm. The amalgam was compacted in the prescribed manner and allowed to age 24 hours. The specimens were then subjected to the standard diametral compression test procedure in "Guide to Dental Materials and Devices" supra, to determine the diametral tensile strength of each specimen. The results are reported in Table 1.

Table 1

Specimen number	Load at fracture (kg)	Specimen length (mm)	Specimen diameter (mm)	Diametral Tensile Kg/mm ²	Strength Psi
1	172.0	7.31	4.00	3.7448	5326
2	197.5	7.025	4.00	4.4744	6364
3	260.5	7.28	4.00	5.6949	8100
4	193.1	7.355	4.00	4.1784	5943
5	243.2	7.07	4.00	5.4747	7786
6	212.4	7.115	4.005	4.7451	6749
7	174.2	7.24	4.00	3.8293	5446
8	200.0	7.43	4.005	4.2787	6085
9	231.8	7.28	4.005	5.0612	7198
10	209.0	7.34	4.005	4.5261	6437

The mean diametral tensile strength was 6,543.6 psi with a standard deviation of 927.2 psi.

The above procedure was repeated but the amalgam specimens were prepared from materials mixed in air. The results obtained are reported in Table 2.

Table 2

Specimen number	Load at fracture (kg)	Specimen length (mm)	Specimen diameter (mm)	Diametral Tensile Kg/mm ²	Strength Psi
11	173.9	7.235	4.00	3.8254	5441
12	228.4	7.79	4.025	4.6373	6596
13	225.6	7.205	4.03	4.9462	7035
14	188.8	7.31	4.04	4.0698	5788
15	109.2	7.37	4.00	2.3581	3354
16	156.2	7.28	4.00	3.4148	4857
17	195.5	7.12	4.00	4.3700	6215
18	208.8	7.25	4.00	4.5836	6519
19	191.6	7.49	4.01	4.0611	5776
20	153.2	6.99	4.00	3.4881	4961

The mean diametral tensile strength was 5,654.2 psi with a standard deviation of 1,071.9 psi.

EXAMPLE 2

Twenty test specimens were prepared following the same procedures (with the exception that the trituration time was 6 seconds) and using the same materials employed in Example 1. The specimens were then subjected to the standard diametral compression test to determine the diametral tensile strength of each specimen. The results are reported in Table 3.

Table 3

Specimen Number*	Load at Fracture (lb)	Specimen length (in)	Specimen diameter (in)	Diametral Tensile Strength (psi)
21	372.0	0.2789	0.1568	5415
22	480.0	0.2781	0.1565	7021
23	345.0	0.2823	0.1564	4974
25	568.0	0.2791	0.1567	8268
26	452.0	0.2823	0.1565	6513
27	512.0	0.2870	0.1562	7270
28	490.0	0.2773	0.1562	7201
29	472.0	0.2837	0.1568	6754
30	252.0	0.2649	0.1565	3869
31	440.0	0.2812	0.1565	6365
32	515.0	0.2835	0.1565	7389
33	507.0	0.2865	0.1567	7189
35	402.0	0.2781	0.1567	5872
36	568.0	0.2815	0.1565	8208
37	555.0	0.2938	0.1570	7659
38	390.0	0.2882	0.1575	5469
39	590.0	0.2852	0.1565	8415
40	360.0	0.2930	0.1565	4998

*Specimen Nos. 24 and 34 were rejected due to incomplete fracture.

The mean diametral tensile strength was 6,603.2 psi with a standard deviation of 1,276.6 psi.

The above procedure was repeated but the amalgam specimens were prepared from materials mixed in air. The results are reported in Table 4.

Table 4

Specimen Number*	Load at Fracture (lb)	Specimen Length (in)	Specimen diameter (in)	Diametral Tensile Strength (psi)
41	441.0	0.2875	0.1565	6239
42	253.0	0.2898	0.1562	3558
43	390.0	0.2802	0.1568	5651
44	440.0	0.2918	0.1567	6126
45	468.0	0.2879	0.1569	6595
46	436.0	0.2855	0.1568	6200
47	515.0	0.2888	0.1564	7258
48	326.0	0.2844	0.1564	4665
49	342.0	0.2890	0.1565	4813
50	507.0	0.2878	0.1563	7175
51	488.0	0.2896	0.1568	6841
52	355.0	0.2878	0.1563	5024
53	492.0	0.2850	0.1563	7031
54	402.0	0.2902	0.1562	5645
55	585.0	0.2913	0.1565	8169
56	403.0	0.2900	0.1565	5652
57	348.0	0.2899	0.1572	4861
58	337.0	0.2847	0.1565	4815
60	477.0	0.2892	0.1563	6718

*Specimen No. 59 was rejected due to incomplete fracture.

The mean diametral tensile strength was 5,949.7 psi with a standard deviation of 1,1143.8 psi.

EXAMPLE 3

20 amalgam test specimens were prepared according to the procedures outlined below. The same commercial capsules containing premeasured amounts of mercury and alloy as in Example 1 were used. Each specimen was prepared from the contents of a single capsule. The caps were removed from the capsules and the caps containing the mercury pouch as well as the capsule body containing the powdered alloy were placed in a dry box. Air was removed from the capsules and alloy powder by evacuation of the dry box. The dry box was then filled with argon. While still in the argon atmosphere in the dry box, the caps were then placed on the capsules and the assembled capsules were then removed from the dry box. The mercury and powdered alloy were mixed together (trituated) in the argon atmosphere, for 6 seconds, using a mechanical (Silamat)

amalgamator oscillating at approximately 4,570 rpm. The amalgam was compacted in the following manner.

Step 1.

- 5 The amalgam was removed from the capsule and divided into five approximately equal increments. Time allowed: 20 seconds.

Step 2.

- 10 Using rubber tipped tweezers, an increment was placed into a standard die cavity and was compacted with one thrust, using a 3 mm dental condenser. Using a 1.5 mm dental condenser, the mass was compacted with fifteen 5 lb thrusts. Time allowed: 25 seconds.

15 Steps 3 and 4.

Step 2 was repeated. The amalgam from each step was placed in the die on top of the amalgam previously placed there.

- 20 Time allowed: 25 seconds for each Step.

Step 5.

Excess mercury was removed with the condenser and a vacuum line.

Time allowed: 10 seconds.

25 Steps 6 and 7.

Repeat Steps 2 and 5.

Time allowed: 35 seconds each for Steps 6 and 7.

Step 8.

- 30 The top surface of the specimen was smoothed with one thrust of the 3 mm diameter dental condenser and the specimen ejected. Time allowed: 5 seconds.

Step 9.

- 35 At the end of one hour, the top end of the specimen was trimmed flat, with the use of a razor blade. After ageing for 24 hours, each specimen was subjected to the standard diametral compression test to determine its diametral tensile strength. The results are reported in Table 5.

Table 5

	Specimen Number*	Load at Fracture (lb)	Specimen length (in)	Specimen diameter (in)	Diametral Tensile Strength (psi)
45	61	486.0	0.2469	0.1582	7921
	62	330.0	0.2522	0.1581	5268
	63	349.0	0.2483	0.1582	5656
	64	299.0	0.2472	0.1588	4849
50	65	384.0	0.2451	0.1575	6332
	66	447.0	0.2460	0.1578	7330
	67	209.0	0.2320	0.1578	3634
	68	259.0	0.2387	0.1578	4377
	69	353.0	0.2365	0.1570	6052
	71	297.0	0.2351	0.1573	5112
55	72	330.0	0.2241	0.1580	5933
	73	425.0	0.2430	0.1573	7078
	75	465.0	0.2341	0.1571	8049
	76	469.0	0.2350	0.1581	8036
	77	358.0	0.2270	0.1579	6358
	78	500.0	0.2378	0.1580	8471
	79	502.0	0.2362	0.1578	8574
60	80	382.0	0.2421	0.1577	6369

*Specimen Nos. 70 and 74 were rejected due to incomplete fracture.

The mean diametral tensile strength was 6,411.5 psi with a standard deviation of 1,455.9 psi.

- 65 The above procedure was repeated but the amalgam specimens were prepared from materials mixed in air. The results are reported in Table 6.

Table 6

Specimen Number	Load at Fracture (lb)	Specimen length (in)	Specimen diameter (in)	Diametral Tensile Strength (psi)
81	371.0	0.2292	0.1578	6530
82	168.0	0.2283	0.1578	2968
83	291.0	0.2257	0.1579	5198
84	356.0	0.2305	0.1580	6223
85	335.0	0.2342	0.1575	5781
86	351.0	0.2395	0.1578	5912
87	300.0	0.2410	0.1579	5018
88	420.5	0.2352	0.1573	7235
89	351.0	0.2533	0.1579	5586
90	155.5	0.2242	0.1579	2796
91	326.0	0.2447	0.1580	5367
92	507.5	0.2470	0.1573	8315
93	397.0	0.2640	0.1580	6059
94	229.0	0.2320	0.1572	3997
95	309.0	0.2451	0.1578	5086
96	402.5	0.2457	0.1580	6600
97	415.0	0.2302	0.1580	7263
98	419.0	0.2517	0.1575	6728
99	489.0	0.2371	0.1578	8320
100	322.0	0.2332	0.1575	5581

The mean diametral tensile strength was 5,828.6 psi with a standard deviation of 1,472.8 psi.

EXAMPLE 4

Two amalgam test specimens were prepared according to the procedure outlined below. The same commercial capsules containing premeasured amounts of mercury and alloy as in Example 1 were used. Each specimen was prepared from the contents of fourteen capsules. The caps were removed from the capsules and the caps containing the mercury pouch as well as the capsule body containing the powdered alloy were placed in a dry box. Air was removed from the capsules and alloy powder by evacuation of the dry box. The dry box was then filled with argon. While still in the argon atmosphere in the dry box, the caps were then placed on the capsules and the assembled capsules were then removed from the dry box. The mercury and powdered alloy were mixed together (tritured) in the argon atmosphere, for 5.5 seconds, using a mechanical (Silamat) amalgamator oscillating at approximately 4,570 rpm. The amalgam was compacted in the following manner.

*Step 1.

- Mercury was introduced into the alloy in each of four capsules.
- Each capsule was then tritured in the described manner.
- The resulting amalgam from the four capsules was placed in a steel die.
- The amalgam was leveled and partially compacted along the sides and ends of the die.
- The amalgam was compacted in a hydraulic press at a hydrostatic pressure of 5,000 psi. The pressure was maintained for 15 seconds. As mercury was expressed, additional hydraulic jack strokes were required to maintain the correct pressure; five such strokes were applied during the 15 second interval.

*The total allowable time between the compaction of two consecutive layers was 3 minutes.

- Excess mercury was removed with a cotton swab.

*Step 2.

Step 1 was repeated. The amalgam from this step was placed on the amalgam in the die from Step 1.

*Step 3.

Step 1 was repeated using only three capsules. The amalgam from this step was placed on the amalgam in the die from the previous steps.

5 *Step 4.

Step 3 was repeated.

Step 5.

The specimen was allowed to cure 24 hours and then ejected from the die.

10 Step 6.

The specimen was polished (using emery cloth) to the following dimensions: $0.197 \times 0.197 \times 1.575$ inches. Approximately 0.007 inch was removed from each cross-sectional direction.

15 Step 7.

Using a mechanical grinder, a groove (test section) was machined on opposing sides of the specimen in order to reduce the cross-sectional area to 0.025 sq. in.

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Each specimen was epoxy cemented into tensile test specimen hold-down pads. The specimens were carefully aligned to minimize bending moments during the tensile test. A cross-head speed of 0.05 inches per minute was used to determine the fracture load under uniaxial stress. The results are reported in Table 7.

*The total allowable time between the compaction of two consecutive layers was 3 minutes.

Table 7

Specimen Number	Uniaxial Tensile Strength (psi)
101	8082
102	8000

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The average uniaxial tensile strength for these specimens was 8,041 psi.

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The above procedure was repeated but the amalgam specimens were prepared from the same materials mixed in air. The results are reported in Table 8.

Table 8

Specimen Number	Uniaxial Tensile Strength (psi)
103	5917
104	6340

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The average uniaxial tensile strength of these specimens was 6,129 psi.

SUMMARY OF DATA

The implications of the data reported in Examples 1-4 can be summarized as in Table 9.

Table 9

Ex. No.	Strength of Air Mixed Specimens (psi)	Strength of Argon Mixed Specimens (psi)	% Strength Increase Using Argon
1	5654±1072	6544±927	15.8
2	5950±1144	6603±1277	11.0
3	5829±1473	6412±1456	10.0
4	6129	8041	31.4

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The foregoing detailed description has been given for clearness of understanding only, and no unnecessary

limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

What is claimed is:

1. In combination:

a closed container,

a mass of a particulate alloy containing silver and tin in the container for use in making dental amalgam, and

an inert atmosphere in the container.

2. A combination according to claim 1 in which the inert atmosphere comprises a gas that does not chemically react with either dental amalgam alloy or mercury either in bulk or in a surface reaction under conditions of normal ambient temperatures or pressures in the absence of applied electrical and magnetic fields.

3. A combination according to claim 2 in which the inert gas is a member of the group consisting of argon, helium, neon and mixtures thereof.

4. A combination according to claim 1 in which the particulate alloy contains at least 65 percent by weight of silver and contains a maximum of 29 percent by weight of tin.

5. An enclosed capsule,

a mass of a particulate alloy containing silver and tin in the capsule for use in making dental amalgam,

a mass of liquid mercury in a separate enclosed rupturable chamber inside of the capsule which keeps the mercury out of contact with the alloy until the chamber is ruptured, and

an inert atmosphere in the container in contact with the alloy.

6. An enclosed capsule according to claim 5 in which the inert atmosphere comprises a gas that does not chemically react with either dental amalgam alloy or mercury either in bulk or in a surface reaction under conditions of normal ambient temperatures or pressures in the absence of applied electrical and magnetic fields.

7. An enclosed capsule according to claim 6 in which the inert gas is a member of the group consisting of argon, helium, neon and mixtures thereof.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,841,467 Dated October 15, 1974

Inventor(s) David A. Hansen

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Page 1, in the list of references, "Brumann" should be
--Baumann--; Column 5, line 50, change "1,1143.8" to
--1143.8--.

Signed and sealed this 3rd day of December 1974.

(SEAL)

Attest:

MCCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents