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71	HERAEUS MEDICAL GMBH

FULL NAME(S) OF INVENTOR(S)	
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TITLE OF INVENTION	
54	BONE CEMENT SYSTEM

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57	Abstract (not more than 150 words) and figure of the drawings to which the abstract refers, are attached.	Number of sheets	22
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Abstract

The invention relates to a bone cement system (100) having a mixing facility (10) for the mixing and dispensing of bone cement, a reservoir container (112) for a monomer, and
5 a conveying means (122), whereby the mixing facility (10) includes a mixing cylinder (20); the mixing cylinder (20) stores a bone cement powder; the monomer can be conveyed from the reservoir container (112) into the mixing cylinder (20) by the conveying means (122); a sieve element is (4) is arranged between the reservoir
10 container (112) and the mixing facility (10) in order to inhibit ingress of the bone cement powder from the mixing cylinder (20) into the conveying means (122); the mixing device (10) includes a dispensing opening (23) for dispensing a bone cement that is mixed from the bone cement powder and the monomer

Figure for publication: Figure 2

HERAEUS MEDICAL GMBH

Figure for Publication

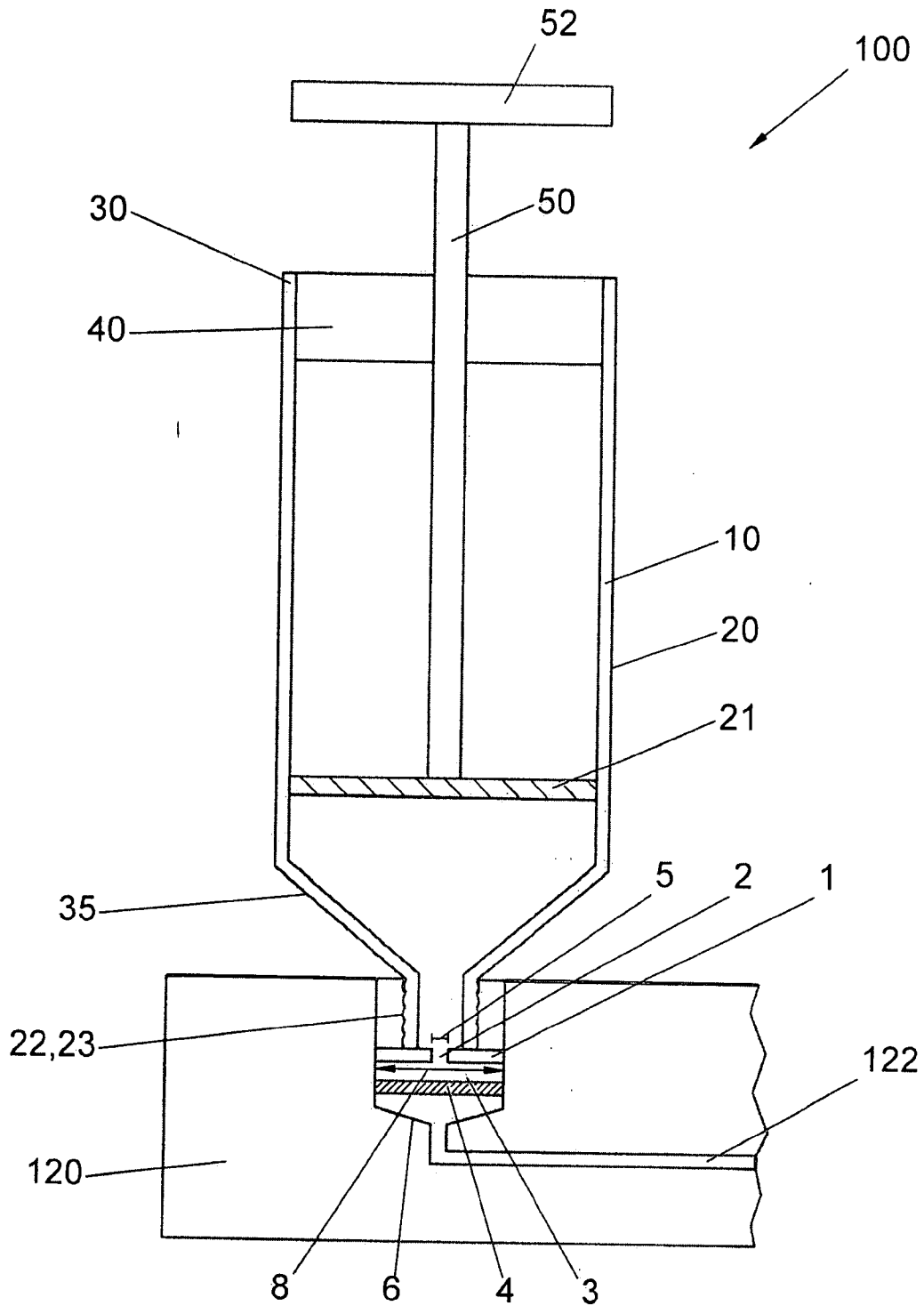


FIGURE 2

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Bone cement system**Field of the Invention**

5 The invention relates to a bone cement system having a mixing facility for the mixing and dispensing of bone cement, a reservoir container for a monomer, and a conveying means, whereby the mixing facility includes a mixing cylinder, the mixing cylinder stores a bone cement powder, the monomer can be conveyed from the reservoir container into the mixing cylinder by means of the conveying means, a sieve element is arranged
10 between the reservoir container and the mixing facility to inhibit the ingress of the bone cement powder from the mixing cylinder into the conveying means, the mixing facility includes a dispensing opening for dispensing a bone cement that is obtained by mixing the bone cement powder and the monomer.

15 Background to the Invention

PMMA bone cements have been known for decades and are based on the groundbreaking work of Sir Charnley (Charnley, J.: Anchorage of the femoral head prosthesis of the shaft of the femur. J. Bone Joint Surg. 42 (1960) 28-30.). The basic
20 structure of PMMA bone cements has remained the same ever since. PMMA bone cements consist of a liquid monomer component and a powder component. The monomer component generally contains the monomer, methylmethacrylate, and an activator (N,N-dimethyl-p-toluidine) dissolved therein. The powder component consists of one or more polymers that are made by polymerization, preferably suspension
25 polymerization, based on methylmethacrylate and co-monomers, such as styrene, methylacrylate or similar monomers, a radio-opaquer, and the initiator, dibenzoylperoxide. When mixing the powder component with the monomer component, swelling of the polymers of the powder component in the methylmethacrylate leads to the formation of a dough that can be shaped plastically. When mixing the powder
30 component with the monomer component, the activator, N,N-dimethyl-p-toluidine, reacts with dibenzoylperoxide while forming radicals. The radicals thus formed trigger the radical polymerization of the methylmethacrylate. Upon advancing polymerization of the

methacrylate, the viscosity of the cement dough increases until the cement dough solidifies.

Polymethylmethacrylate bone cements can be mixed in suitable mixing beakers by means of spatulas by mixing the cement powder with the monomer liquid. This procedure is disadvantageous in that inclusions of air may be present in the cement dough thus formed and may later cause destabilization of the bone cement - also referred to as cement. For this reason, it is preferable to mix bone cement powder with the monomer liquid in vacuum mixing systems, since mixing in a vacuum removes inclusions of air from the cement dough all but completely and thus attains optimal cement quality (Breusch SJ et al.: Der Stand der Zementiertechnik in Deutschland. Z Orthop. 1999, 137: 101-07). Bone cements mixed in a vacuum have substantially lower porosity and thus show improved mechanical properties. A large number of vacuum cementing systems have been disclosed of which the following shall be named for exemplary purposes: US6033105 A, US5624184 A, US4671263 A, US4973168 A, US5100241 A, WO99/67015 A1, EP1020167 A2, US5586821 A, EP1016452 A2, DE3640279 A1, WO94/26403 A1, EP0692229 A1, EP1005901 A2, US5344232 A.

A further development are cementing systems in which both the cement powder and the monomer liquid are already packed in separate compartments of the mixing systems and are mixed with each other in the cementing system only right before application of the cement (US5997544 A, EP0692229 A1, US6709149 B1). A drawback of all of these systems is the transfer of the monomer liquid into the cement powder and the complete mixing of these two components to obtain a homogeneous cement dough which must, in particular, not contain any regions of cement powder that has not been wetted by the monomer liquid. In a mixing system that is currently on the market in Europe, tubes that are arranged on the side of the lower part of the cartridge and penetrate through the cartridge wall are used to introduce the monomer liquid approximately into the middle of the cement powder through the application of a vacuum. There is no mixing facility provided at the tubes that might inhibit the ingress of cement powder into the tubes during storage of the mixing system. Clogging of the tubes by cement powder cannot be excluded completely.

Another mixing system for the mixing and dispensing of bone cement is shown in DE 698 12 726 T2. The mixing system includes a mixing cylinder, whereby a sieve element is arranged between the reservoir container and the mixing facility to inhibit ingress of the bone cement powder from the mixing cylinder into the conveying means. Said
5 mixing systems have proven to be disadvantageous in that homogeneous and rapid mixing of the monomer and the bone cement powder cannot be ensured at all times.

Another variant was disclosed in EP 1 140 234 B1. In said mixing system, the monomer liquid is aspirated through the entire cement powder by means of a vacuum. The basic
10 approach, i.e. to aspirate the monomer liquid through the entire cement powder in order to achieve optimal mixing and inhibit regions of non-wetted cement powder from forming is feasible only if a cement powder is used that swells very slowly after being wetted by the monomer liquid. This means that the high and medium viscosity PMMA bone cements, which currently are most commonly used in endoprosthetics, can be used not
15 at all or with difficulties since the cement powder of these cements swells immediately after being wetted by the monomer liquid and forms a dough that renders further pervasion of the cement powder by the monomer liquid difficult or even impossible.

Accordingly, a need exist for developing a bone cement system that is not associated
20 with the aforementioned disadvantages, but is, in particular, protected against clogging by cement powder.

Summary of the Invention

25 According to the invention, there is provided a bone cement system having a mixing facility for the mixing and dispensing of bone cement, a reservoir container for a monomer, and a conveying means, whereby the mixing facility includes a mixing cylinder; the mixing cylinder stores a bone cement powder; the monomer can be conveyed from the reservoir container into the mixing cylinder by the conveying means;
30 a sieve element is arranged between the reservoir container and the mixing facility in order to inhibit ingress of the bone cement powder from the mixing cylinder into the

conveying means; the mixing device includes a dispensing opening for dispensing a bone cement that is mixed from the bone cement powder and the monomer; wherein

the dispensing opening includes a shield having at least one through-opening; and

a ratio of an area of the through-opening to the area of the sieve element is at least 1 to 3, and a distance between the shield and the sieve element is at least 1 mm.

The invention allows the injection of monomer liquid from below into the bone cement powder - also referred to as cement powder - such that the injection system is inhibited from becoming sticky, and mixing of the cement powder, as completely as possible, can be achieved. The bone cement system must not get sticky since this renders complete monomer transfer from the monomer reservoir container into the cement powder impossible. The result of incomplete monomer transfer would be that only a fraction of the intended monomer would form a dough with the cement powder. The resulting dough would therefore be more viscous and the bone cement - also referred to as cement - would have unpredictably changed mechanical properties after it hardens as compared to correctly mixed cement that is produced to have a predetermined ratio of monomer liquid to cement powder. The bone cement system works such that the application of a vacuum opposite from the through-opening generates a negative pressure in the feed opening and first the residual air present in the system and then the monomer liquid is aspirated into the intervening space. The air arriving first moves through the sieve element and carries along the cement powder that is present in the intervening space through the through-opening in the direction of the mixing cylinder. As a result, the intervening space no longer contains cement powder and is empty. Subsequently, the monomer liquid is aspirated through the sieve element. Accordingly, the sieve element facilitates the bone cement powder not flowing into the conveying means and clogging same upon contact with the monomer liquid. Therefore, according to the invention, the sieve element separates the conveying means and the mixing cylinder such that no bone cement powder can flow into the conveying means.

In an advantageous further development variant of the bone cement system according to the invention the mixing facility includes a dispensing opening for dispensing a bone cement that is mixed from the bone cement powder and the monomer. A bone cement forms after mixing of the bone cement powder and the monomer. Before it hardens, said bone cement needs to be dispensed from the bone cement system and, preferably, implanted into the patient. It has proven to be advantageous for this purpose to have a dispensing opening being present through which the bone cement can be pressed from the mixing cylinder. Advantageously, the dispensing opening is designed to be funnel-shaped. In another advantageous further development the sieve element is stored in an intervening space that can be connected to the dispensing opening of the mixing facility and in which the conveying means ends. Both the dispensing opening of the mixing facility and the conveying means end in the intervening space. Accordingly, the monomer flows from the reservoir container through the intervening space into the mixing cylinder. The sieve element according to the invention is arranged in said intervening space. This embodiment is advantageous in that the sieve element is not arranged in said dispensing opening through which the mixed bone cement is dispensed later on. However, the sieve element inhibits the bone cement powder from flowing from the mixing cylinder into the conveying means.

In yet another advantageous further development the sieve element has a mesh size of less than 30 μm , in particular a mesh size between 5 μm and 25 μm . Said mesh size ensures, on the one hand, that the bone cement powder cannot flow from the mixing facility into the conveying means. On the other hand, the flow of the monomer, in particular liquid monomer, from the reservoir container into the mixing cylinder is impeded only to a minor degree by the mesh of the sieve element. Accordingly, a sieve element with a mesh size between 30 μm and 5 μm represents a connection element between the reservoir container and the mixing facility that is open only on one side.

In another advantageous further development, the dispensing opening includes a shield with at least one through-opening. Advantageously, the shield is arranged between the mixing facility, in particular the dispensing opening, and the sieve element. In this context, the dispensing opening determines the quantity of monomer that can flow into

the mixing cylinder in a unit of time. Advantageously, the area of the through-opening is smaller than the area of the sieve element. Advantageously, the sieve element and the shield are part of the intervening space. Adjacent to said intervening space, there is, on the one hand, the conveying means of the reservoir container and, on the other hand, the dispensing opening of the mixing facility. The intervening space is designed such that it stores, approximately in the middle thereof, the sieve element, which is arranged essentially parallel to the shield. During storage and transport of the polymethylmethacrylate bone cement mixing system, the sieve element inhibits penetration of the cement powder in the direction of the feed opening. The bone cement system works such that the application of a vacuum opposite from the through-opening generates a negative pressure in the feed opening and first the residual air that is present in the system and then the monomer liquid is aspirated into the intervening space. The air arriving first moves through the sieve element and carries along the cement powder that is present in the intervening space through the through-opening in the direction of the mixing cylinder. The intervening space then no longer contains cement powder and is substantially empty. Subsequently, the monomer liquid is aspirated through the sieve element. Due to the low mesh size of the sieve element, this causes a marked reduction of the flow rate. To counteract this loss in velocity, the area of the sieve is made correspondingly large. This means that the volume flow is not impeded despite the slower flow rate of the liquid through the sieve element due to the large area thereof. The term, volume flow, is understood to mean the volume of monomer liquid per unit time that emanates from the feed opening. Subsequently, the monomer liquid accumulates in the intervening space and moves in the direction of the through-opening.

In the bone cement system according to the invention a ratio of an area of the through-opening to the area of the sieve element is at least 1 to 3. Preferably the ratio of the area of the through-opening to the area of the sieve element is between 1 to 4 and 1 to 20. The area of the through-opening being small compared to the area of the sieve element accelerates the liquid in the dispensing opening in order for the volume flow to be constant. This means that a jet of monomer liquid is generated that is injected into the cement powder that is situated above the through-opening. The jet of monomer

spreads in a funnel shape with increasing distance of travel. Due to the high velocity of the monomer jet, the monomer can pass through the cement powder in a sufficiently short time before the cement powder swells to any significant degree. Bone cement powder particles that have already swelled are displaced by the monomer jet.

5

Inhibiting an ingress of bone cement powder from the mixing cylinder into the conveying means is promoted by a distance between the shield and the sieve element being at least 1 mm, preferably by the distance between the shield and the sieve element being between 2 mm to 10 mm. The values specified above have been found surprisingly in
10 extensive measurements to be particularly preferred in order to ensure that the monomer entering the mixing cylinder, on the one hand, carries along possible bone cement powder residues from the intervening space into the mixing cylinder, and, on the other hand, does not provide the intervening space too large such that the amount of bone cement powder residues that is deposited therein is as small as possible.

15

Depending on the bone cement powder that is used, it has proven to be advantageous for the through-opening to be provided to be circular, oval, star-shaped or slit-shaped, in particular for the shield to extend in a funnel shape. The shapes of the through-opening can control the flow behavior of the monomer into the bone cement powder. In particular
20 star- or slit-shaped through-openings provide for a funnel-shaped spreading of the jet of monomer liquid that enters through the shield into the mixing cylinder. In addition, the shield can extend to be funnel-shaped. In this case, the shield works like a Venturi nozzle and effects additional acceleration of the monomer liquid that flows from the intervening space into the mixing cylinder.

25

In order to mix the monomer with the bone cement powder as homogeneously as possible, it has proven to be advantageous for a mixing plunger to be arranged in the mixing cylinder, whereby the mixing plunger can be moved axially by means of an actuation rod that is guided to exit in a sealed manner at a first cylinder end.

30

Advantageously, the first cylinder end is situated opposite from a second cylinder end, whereby the second cylinder end includes the dispensing opening. Accordingly, the monomer flowing into the mixing cylinder can be pulled even further into the mixing

cylinder by means of the mixing plunger and/or the actuation rod in order to promote homogeneous mixing of the cement powder and the monomer.

One particularity of the mixing facility according to the invention is that the plunger system can be pushed axially into the mixing cylinder in order to dispense a bone cement that is mixed from the bone cement powder and the binding agent, in particular the monomer, through the dispensing opening. The dispensing opening is situated at a second cylinder end of the mixing plunger. The second cylinder end is situated opposite from the first cylinder end. During dispensing, the plunger system is pushed from the direction of the first cylinder end in the direction of the second cylinder end and, in turn, presses the ready-mixed bone cement through the dispensing opening. In an advantageous further development, the dispensing opening includes a connection means, in particular a connection thread. Said connection thread can be used to screw the mixing cylinder into the bone cement system and/or to connect the mixing cylinder to a hose system via which the ready-made bone cement can be introduced into the bone. An applicator gun into which the mixing cylinder is to be clamped can be used for this activity. For ease of use of the applicator gun, the actuation rod can include a predetermined breakage point such that the actuation rod can be broken off at a defined place. For dispensing the ready-mixed bone cement, the actuation rod is pulled in the direction of the plunger system until the mixing plunger touches against the plunger system. The plunger system, including the mixing plunger that touches against it in front of it, can be pressed into the mixing cylinder by then breaking off the actuation rod.

In an advantageous further development, the dispensing opening includes a connection means, in particular a connection thread. Said connection thread can be used to screw the mixing cylinder into the bone cement system to be described below and/or to connect the mixing cylinder to a hose system via which the ready-made bone cement can be introduced into the bone. An applicator gun into which the mixing cylinder is to be clamped can be used for this activity. For ease of use of the applicator gun, the actuation rod can include a predetermined breakage point such that the actuation rod can be broken off at a defined place. For dispensing the ready-mixed bone cement, the actuation rod is pulled in the direction of the plunger system until the mixing plunger

touches against the plunger system. The plunger system, including the mixing cylinder that touches against it in front of it, can be pressed into the mixing cylinder by then breaking off the actuation rod.

- 5 Moreover, it is advantageous for the reservoir element to store a reservoir container for the monomer. For production of the bone cement, the monomer must be introduced into the bone cement powder. The bone cement then hardens after a certain period of time. It is therefore obvious that the bone cement cannot be delivered such as to be in the device and ready for dispensing. It is therefore necessary for the bone cement powder
10 and the monomer to be stored separately until shortly before dispensing of the bone cement. It is therefore expedient if the reservoir element includes a reservoir container for the monomer. Glass containers, in particular, that are used as reservoir containers for the binding agent, in particular the monomer, have proven to be easy to disinfect. The reservoir element can include a valve means to control the inflow of the monomer.
15 Said valve means controls and/or triggers the inflow of the monomer from the reservoir container into the device according to the invention.

- In an advantageous further development of the bone cement system according to the invention the bone cement system includes a base element, whereby the base element
20 stores the mixing facility and the reservoir container. The base element therefore serves as platform both for the mixing facility according to the invention and for the reservoir element for the binding agent. The mixing facility according to the invention and the reservoir element can be arranged at and/or on the base element as some kind of foundation of the bone cement system. In an advantageous development of the bone
25 cement system according to the invention the base element includes a coupling means for a non-positive and/or positive fit connection to the mixing facility, in particular to a dispensing opening of the mixing facility. Since the mixing facility according to the invention is also to be used for dispensing the bone cement, it is advantageous for the mixing facility to be reversibly separable from the base element. This can be attained by
30 means of the coupling element according to the invention. The coupling element advantageously is a thread onto which the dispensing opening of the mixing facility can

be screwed. This provides a secure connection between the base element and the mixing facility.

5 In another advantageous development, the base element can store the conveying means. In this case, the conveying means extends through the base element. The intervening space can also be arranged in the base element. By means of the connection means, it is feasible to connect the intervening space, and thus the conveying means, to the mixing cylinder. In this context, according to the invention, the sieve element inhibiting ingress of the bone cement powder from the mixing cylinder
10 into the conveying means is arranged in the intervening space.

Further measures and advantages of the invention are evident from the claims, the following description, and the drawings.

15 Detailed Description of the Invention

The invention will now be described by way of the following non-limiting multiple exemplary embodiments with reference to the accompanying drawings.

20 In the figures:

Fig. 1 shows a schematic sectional drawing of a bone cement system according to the invention;

25 Fig. 2 shows a schematic sectional drawing of a mixing facility according to the invention; and

Fig. 3 shows a schematic sectional drawing of a dispensing opening of the mixing facility.

30

Figure 1 shows a bone cement system 100 according to the invention. The bone cement system 100 includes a mixing facility 10 for mixing and dispensing bone

cement. Said mixing facility 10 is stored on a base element 120 in the exemplary embodiment shown. Said base element 120 also carries a reservoir element 110 for a monomer. The bone cement system 100 serves for mixing the bone cement. For this purpose, bone cement powder is filled into a mixing cylinder 20 of the mixing facility 10.

5 Said bone cement powder can subsequently be mixed with the monomer in order to form bone cement. As illustrated in Figure 1, reservoir element 110 is part of the bone cement system. Reservoir element 110 stores a reservoir container 112 for the monomer. An outflow of the monomer from the reservoir container 112 can be controlled and/or triggered via a valve means 115. Advantageously, the reservoir

10 container 112 is a glass container that is opened in its head region by the valve means 115. The monomer then flows through a conveying means 122 from the reservoir container 112 into the mixing cylinder 20. The transfer flow of the monomer is increased since a negative pressure is present in the mixing cylinder 20. The bone cement powder and the monomer can then be mixed easily and simply by means of the actuation rod

15 and the mixing plunger 21. After mixing is completed, the facility 10 can be unscrewed from the base element 120. For this purpose, the base element 120 includes a coupling means 121 that acts in concert with a connection means 22 of the mixing plunger. After separation of the mixing facility 10 from the base element 120 is effected, the actuation rod 50 is shifted axially such that the mixing plunger 21 comes to rest against the

20 plunger system 40. Subsequently, the actuation rod can be snapped off at the predetermined breakage point 51. The mixing facility 10 can now be integrated into a cementing gun. Actuation of the cementing gun moves a toothed rack with collar in the direction of the plunger system 40. The plunger system 40 is used for dispensing the bone cement. For this purpose, the plunger system 40 is designed to be axially movable

25 and can be pressed axially into the mixing cylinder 20. This allows the bone cement formed by mixing the bone cement powder and the monomer to be dispensed through a dispensing opening 23.

The prior art knows bone cement systems, in which the monomer liquid is stored in

30 containers on the side of the mixing cylinder. Tubes are used to introduce the monomer liquid approximately in the middle of the cement powder that is arranged in the mixing cylinder. It has proven to be disadvantageous that the arrangement and design of the

tubes do not completely exclude clogging of the tubes by cement powder. This can lead to the supplied amount of monomer being insufficient and a non-homogeneous bone cement region may result therefrom. In order to overcome this disadvantage, the bone cement system 100 according to the invention includes a sieve element 4, like the one
5 shown in Figure 2. Said Figure 2 is a sectional drawing analogous to the one in Figure 1 with the features in the area of the dispensing opening 23 being shown in more detail. As is evident, the base element 120 stores the mixing cylinder 20 of the mixing facility 10. The mixing cylinder 20 is connected to the base element 120 by means of a connection means, a thread in the present case. A shield 1 that includes at least one
10 through-opening 2 is situated below the dispensing opening 23 in the base element. It is evident that the through-opening has a width and therefore an area 5 that is clearly smaller than the area of the sieve element 4 that is arranged underneath. The width thereof is indicated by reference number 8. Advantageously, the area of the through-opening is $1/4$ to $1/20$ of the area of the sieve element 4. The sieve element 4 inhibits
15 bone cement from the mixing cylinder 20 from penetrating into and clogging the conveying means 122 during storage and transport. When the finished bone cement is to be mixed, the bone cement system is connected to a vacuum element. This generates a negative pressure in the mixing cylinder 20 and in an intervening space 3 that stores the sieve element 4. Said negative pressure aspirates residual air from the
20 intervening space 3 in the direction of the vacuum connection, which is generally arranged in the area of a first cylinder end 30. Said aspiration of the residual air causes any cement powder that is still present in the intervening space 3 to be aspirated through the through-opening 2 of the shield 1 in the direction of the mixing cylinder 20. Subsequently, the monomer liquid can be aspirated through the sieve element 4. In the
25 process, the sieve element 4 advantageously has a mesh size of less than $30\text{ }\mu\text{m}$. Due to this small mesh size of the sieve element 4, the flow rate of the monomer is reduced. In order to still achieve homogeneous passage of the liquid of the monomer into the mixing cylinder 20, the size of the sieving area 4 must be adapted accordingly. The ratio of the area 5 of the through-opening 2 to the area 8 of the sieve element 4 thus also
30 determines the volume of a monomer liquid that is aspirated into the mixing cylinder 20 in a unit of time. Accordingly, the use, according to the invention, of the sieve element 4

promotes homogeneous ingress of monomer into the mixing cylinder 20 and simultaneously inhibits clogging of the conveying means 122 by bone cement powder.

Figure 3 shows another detail magnification of the intervening space 3 with the integrated sieve element 4 that serves to inhibit ingress of the bone cement powder from the mixing cylinder 20 through the through-opening 3 into the conveying means 122. The intervening space 3 has a V-shaped base 6 that has the effect of a nozzle on the monomer flowing from the conveying means 122. The sieve element 4 is arranged above said dispensing opening of the conveying means 122. Said sieve element can be a punched, woven or knitted structure that is composed of metals, plastic materials and/or combinations thereof.

Reference numbers

15	1	Shield
	2	Through-opening
	3	Intervening space
	4	Sieve element
	5	Width of the through-opening
20	6	Base of the intervening space
	8	Width of the sieve element
	10	Mixing facility
	20	Mixing cylinder
	21	Mixing plunger
25	22	Connection means
	23	Dispensing opening
	30	First cylinder end
	35	Second cylinder end
	40	Plunger system
30	50	Actuation rod
	51	Predetermined breakage point
	52	Handle

	100	Bone cement system
	110	Reservoir element
	112	Reservoir container
	115	Valve means
5	120	Base element
	121	Coupling means
	122	Conveying means

10 It is to be appreciated, that the invention is not limited to any particular embodiment or configuration as hereinbefore generally described or illustrated.

The claims which follow are to be considered an integral part of the present disclosure. Reference numbers (directed at the drawings) shown in the claims serve to facilitate the correlation of the integers of the claims with illustrated features of the preferred
15 embodiment(s), but are not intended to restrict in any way the language of the claims to what is shown in the drawings, unless the contrary is clearly apparent from the context.



Claims

1. A bone cement system (100) having a mixing facility (10) for the mixing and dispensing of bone cement, a reservoir container (112) for a monomer, and a conveying means (122), whereby

the mixing facility (10) includes a mixing cylinder (20);

the mixing cylinder (20) stores a bone cement powder;

the monomer can be conveyed from the reservoir container (112) into the mixing cylinder (20) by the conveying means (122);

a sieve element (4) is arranged between the reservoir container (112) and the mixing facility (10) in order to inhibit ingress of the bone cement powder from the mixing cylinder (20) into the conveying means (122);

the mixing device (10) includes a dispensing opening (23) for dispensing a bone cement that is mixed from the bone cement powder and the monomer;

wherein

the dispensing opening (23) includes a shield (1) having at least one through-opening (2); and

a ratio of an area of the through-opening (2) to the area of the sieve element (4) is at least 1 to 3, and a distance between the shield (1) and the sieve element (4) is at least 1 mm.

2. A bone cement system (100) as claimed in claim 1, wherein the sieve element (4) is stored in an intervening space (3) that is connectable to the dispensing

opening (23) of the mixing facility (10) and in which the conveying means (122) ends.

3. A bone cement system (100) as claimed in claim 1 or claim 2, wherein the sieve element (4) has a mesh size of less than 30 μm .

4. A bone cement system (100) as claimed in any one of the preceding claims, wherein the sieve element (4) has a mesh size of between 5 μm and 25 μm .

5. A bone cement system (100) as claimed in any one of the preceding claims, wherein the ratio of the area of the through-opening (2) to the area of the sieve element (4) is between 1 to 4 and 1 to 20.

6. A bone cement system (100) as claimed in any one of the preceding claims, wherein the distance between the shield (1) and the sieve element (4) is between 2 mm to 10 mm.

7. A bone cement system (100) as claimed in any one of the preceding claims, wherein the through-opening (2) is a shape selected from the group including: circular, oval, star-shaped, and slit-shaped; and wherein the shield (1) extends in a funnel shape.

8. A bone cement system (100) as claimed in any one of the preceding claims, wherein a mixing plunger (21) is arranged in the mixing cylinder (20), whereby the mixing plunger (21) is displaceable axially by means of an actuation rod (50) that is guided to exit in a sealed manner at a first cylinder end (30).

9. A bone cement system (100) as claimed in any one of the preceding claims, wherein a plunger system (40) is displaceable axially into the mixing cylinder (20) in order to dispense a bone cement that is mixed from the bone cement powder and the monomer through the dispensing opening (23).

10.A bone cement system (100) as claimed in any one of the preceding claims,
wherein the reservoir element (110) includes a valve means (115) in order to
control and/or trigger an outflow of the monomer from the reservoir container
(112).

5

11.A bone cement system (100) as claimed in any one of the preceding claims,
wherein the bone cement system (100) includes a base element (120), whereby
the base element (120) stores the mixing facility (10) and the reservoir container
(112).

10

DATED AT PRETORIA THIS 26TH DAY OF JULY 2010.



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HAHN & HAHN INC.

APPLICANT'S ATTORNEYS

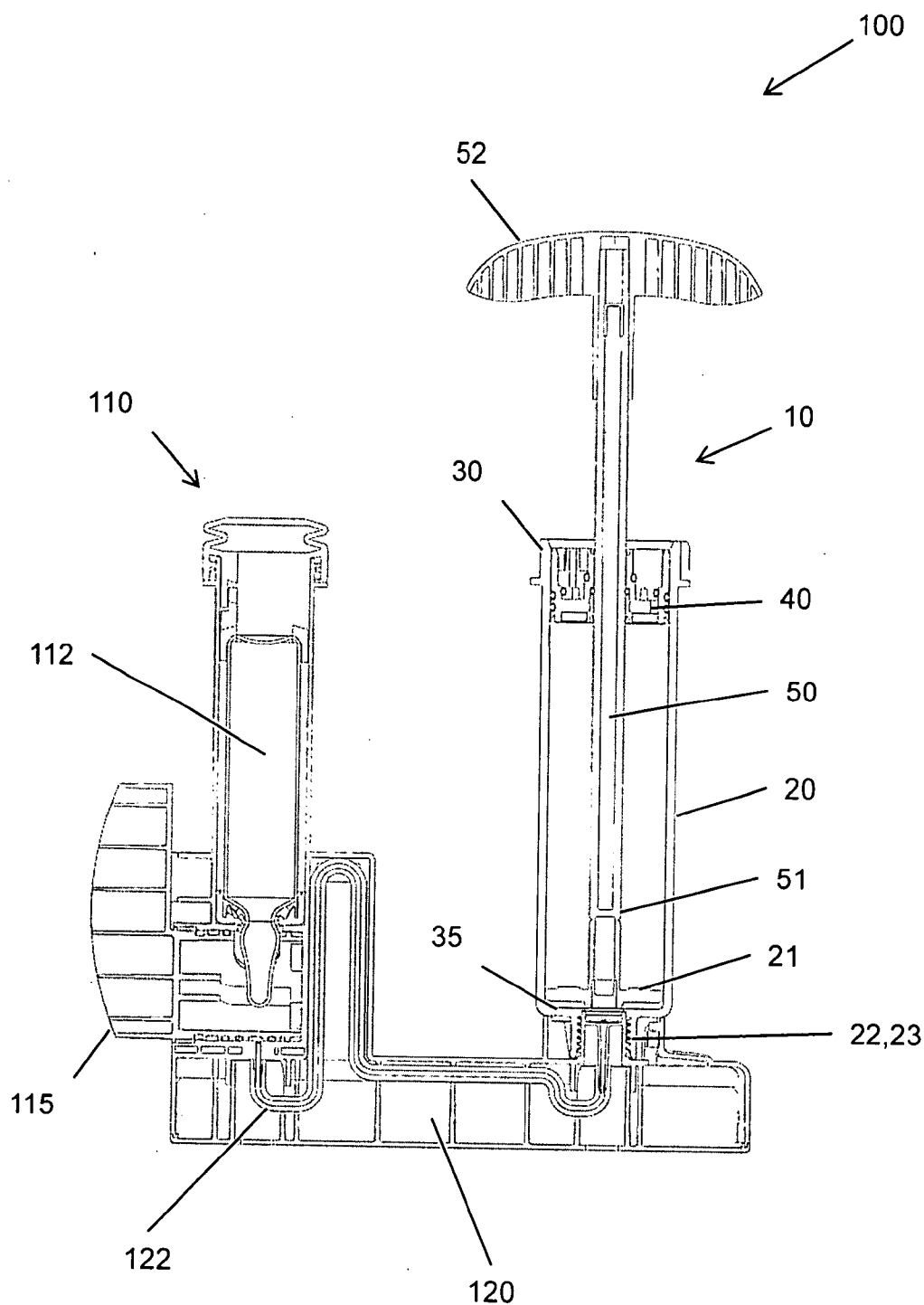
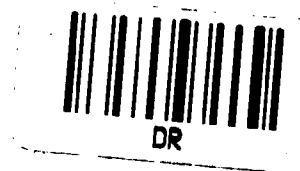
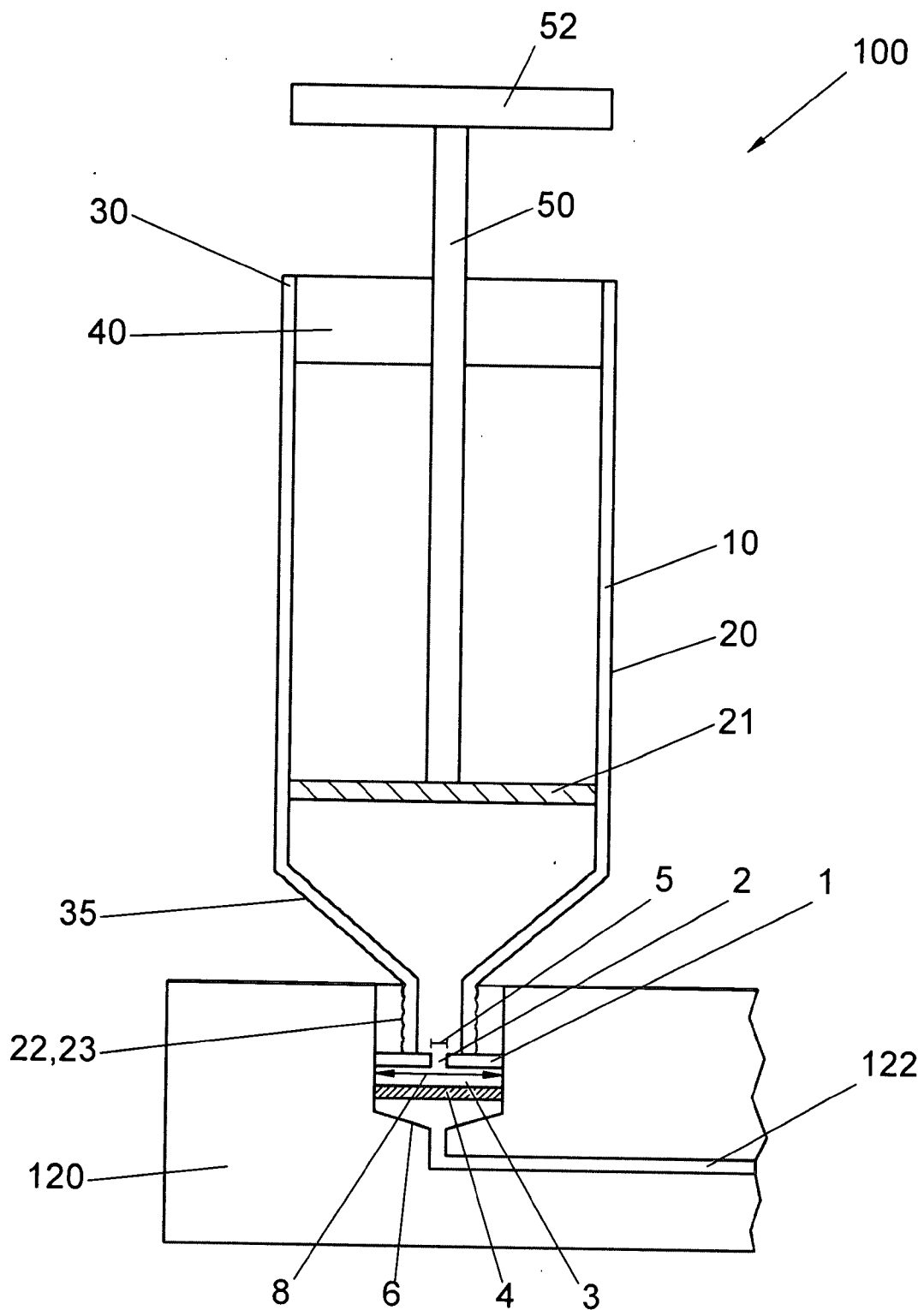


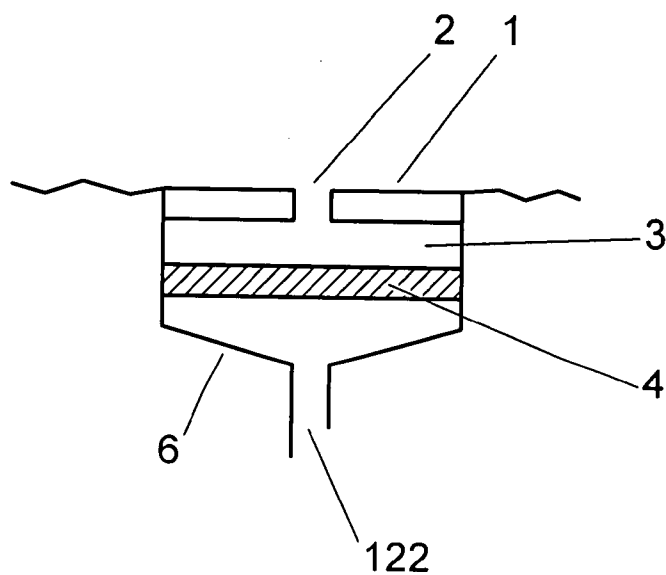
Fig. 1

Bernolt
HAHN & HAHN INC.
APPLICANT'S AGENT



Remdt
HAHN & HAHN INC.
APPLICANT'S AGENT

Fig. 2



Berndt
HAHN & HAHN INC.
APPLICANT'S AGENT

Fig. 3