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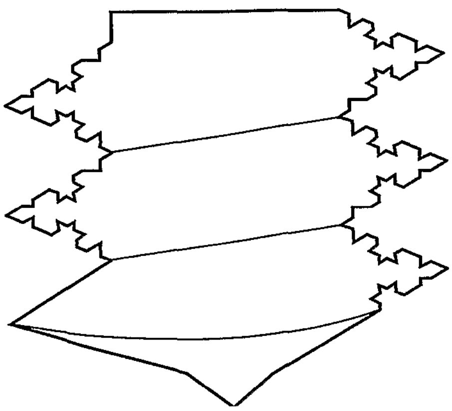
(54) Title: BONE IMPLANT SCREW WITH INCREASED BONE-IMPLANT INTERFACE



(57) Abstract: The present invention relates to a bone implant screw with increased bone-implant interface, characterised in that it has at least a side of the thread profiled.

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Bone implant screw with increased bone-implant interface

The present invention relates to a bone implant screw with increased bone-implant interface.

More specifically, the invention relates to an implant of the above kind permitting combining the need of obtaining a sufficient primary stability and of optimising the surface available for bone integration of the implant.

Both for dentistry and for other applications there is a need for screws for bone implants which enable the bone tissue to re-grow around the screw; such screws must provide sufficient primary stability – the screw must not move straight after insertion (requirement A) and at the same time must provide a sufficient surface for initial osteosynthesis – in such a way as to allow for the formation of "osteoblastic chambers" referred to as "wound chambers" and from now onwards referred to as "chambers" (requirement B).

It is further already known that following the insertion of a screw into bone tissue micro- and macro- cavities are created around the screw and these "osteoblastic cavities" where in the very first days after the operation the newly formed bone begins.

The current state of the technique is concentrated around variations through a technique known by the acronym SLA, "Sand blasting with Large grit followed by Acid etching". This gives the surface of the screw a coarseness which makes it possible to have an optimum stabilisation of the coagulum which is followed by the formation of granulation tissue that is replaced by a provisional matrix and finally by new bone.

The degree of coarseness, which is obtained, is less than 10 micrometers (to be found in medical literature).

It is nevertheless evident that, given the same dimensions of the screw and grade and type of coarseness, the final stability of the implant (maintenance phase) depends on the implant-bone interface.

The surface of a general screw can be described as consisting of a thread and a part of the shaft where there is no thread; this latter part may not exist as in the case where the thread covers the shaft completely.

Object of the present invention is that of suggesting a solution for a screw whose structure is designed to maximise these two requirements A and B described above.

The solution according to the present invention concerns a variation both local and overall in the profile of the surfaces of the thread or the shaft of a general type of bone implant screw, of a type that will remain permanently in the base of the implant.

These and other results are obtained according to the present invention by a bone implant screw with increased bone-implant interface, characterised by profiling a side of the thread.

Further features of the screw according to the invention are described in the dependent claims 2 – 26.

The present invention will be now described, for illustrative but not limitative purposes, according to its preferred embodiments, with particular reference to the figures of the enclosed drawings, wherein:

figure 1A schematically shows a thread of an endosseous screw;

figure 1A is a section view of the screw of figure 1;

figure 1B schematically shows thread of figure 1A with three in-line tapping elements with increasing dimensions, the sections of which are shown in figures $1B_{s1}$, $1B_{s2}$, $1B_{s3}$,

figure 2C schematically shows thread of figure 1A with three in-line tapping elements with increasing dimensions on both faces, the section of which is shown in figure $2C_1$,

figure 1D schematically shows another thread of figure 1A with three in-line tapping elements with increasing dimensions on both faces, the section of which is shown in figure $1D_1$,

figures 2.E1, 2.E2, w.E3a, 2.E3b, 2.F1, 2.F2a, 2.F2b show embodiments of projecting surfaces for increasing the screw – bone contact surface,

figures 2.G1, 2.G2, 2.G3 and 2.G4 schematically show the shape of profile that can be obtained,

figures 3A, 3H, 3I, 3J and 3K, 4M, 4N and 4O show embodiments of the system according to the invention.

Observing the figures of the enclosed drawings, figure 1 shows a typical thread of a ostheosynthesis screw. Such a type of screw is illustrated in Figure 1.A.

As already said, the solution suggested according to the present invention aims to introduce modifications to the surface of the screw in order to satisfy the requirements A and B mentioned above.

Since it is clear that the overall dimensions of the screw cannot vary so much since the dimensions depend on the bone to which it is to be attached, this invention is for the overall surface of the interface between the implant and the surrounding bone tissue to be increased by increasing the macroscopic and/or microscopic surface of the thread itself, of the shaft or both by applying one or more incisions to one or both faces of the thread or to the shaft, parallel to but not on the same plane as the thread by placing on the thread and/or on the shaft tapping elements which are able to make incisions into the bone as the implant is being fitted, and/or by placing on the thread elements in relief which can be inserted into the tracks left by the tapping elements.

Before going into mathematical detail it is important to state first that incisions made on the surface of the screw can, in some cases be favourable to requirement A (primary stability) or requirement B (newly formed bone). In fact an incision that starts at the bottom part of the screw will have a combined screw-bone profile as shown in Fig.3.H4, whilst in the opposite case the profile will be as in Fig.3 H3. In the first case requirement A is satisfied whilst in the second case requirement B will be satisfied.

It must be emphasised that the numerical data is relative to a section which is perpendicular to the plane of the thread in the direction as indicated by the line ø on Fig. 3.H1 (if you consider only the central part in heavy type) and/or in general perpendicular to the main direction of the incision.

Since its purpose is to increase to maximise the surface, such an incision is structured according to the principles of the fractal curves Koch. As can be seen in the drawing in section 1.As, the section of a screw shows that the edge of the thread is represented by two of the three sides of a triangle, which for simplicity's sake will assume to be equilateral. The field of application of this invention should not be limited by this assumption, but it is understood that the angle at the outermost vertex of the thread can be any angle as in the case of those at the base of the thread. Furthermore the edges of the thread are not necessarily in a straight line.

In the details 3.J(1), 3.J(2) and 3.J(3), the darker part Y represents the thread, the grey rectangle X the shaft of the screw. The detail 3.J(1) shows sides (a,b) and (b,c) of the triangle, each one with a length of zl, representing the edges of the thread of the screw seen in section. If a unitary value is assigned to each side the surface is proportional to 2:

s (thread)$\propto$ 2.

If we now divide each of the sides into 3 parts and we substitute the central part with an angle (which we will define as the angle of the first order) consisting of two sides with a length equal to that of the part, which we have just taken out (Procedure 1, first application). The resulting outline which can be seen in Fig. 3.J(2) has become 8/3 which is also the proportional factor of the area of the surface of the entire thread:

s´(thread) $\propto$ 8/3

In other words the outline is made up of eight elements of length z2, shown in Fig. 3.J(2), each one of which has a length equal to a third of the original.

The increase has therefore been of 2/3 of the length of one side , which corresponds to an increase in the surface of the thread of 33% (Result 1); each side therefore contributes 16.6% (Result 2).

If now the preceding operation is repeated (division of each straight line into three, elimination of the central segment and construction of an angle – defined as of second order - with sides equal to the segment eliminated; Procedure 1, second application), the segments have unit length equal to 1/9 of the original, which brings the final length of the outline of the section of the thread to:

s´´(thread) $\propto$ 32/9

All this (outline and segment z3) is shown in Fig. 3.J(3).

The increase from the initial situation (two sides, therefore 18/9) is equal to 7/9, equal to almost 78%, or more precisely 77.77% (Result 3). In other words the ratio between 32 and 18 small segments of unitary length is 1.777...

1.A is a three dimensional drawing of a screw focusing on the thread; 1.As shows a section through the same screw.

3.H1 shows the same screw on which, on one of the two sides of the thread, an incision has been made in accordance with the initial phase as described relating to Result 1; this single incision increases the area of the thread by 16.66...%.

3.H2 shows the screw with part of the shaft visible, and on this part Procedure 1 has been carried out.

Drawings 3.I are sections:

3.I(s0) is the section shown in Fig. 3.H1.

3.I(s1) is a section of the screw in the case described of the first application of Procedure 1 and both faces of the thread.

3.I(s2) is a section of the screw in the case described of the second application of Procedure 1 and both faces of the thread.

Figures 3.J show in greater detail the sections of the screws referred to in the preceding paragraphs and in all of them Y represents the thread and X the central shaft of the screw.

3.J(1) is the section of 1.A in which the points (a,b,c) describe the outline of the section of the spiral of the thread. In the lower part the detail zl shows the length of the side of the section; in other words,

$$zl = \overline{a,b}$$

3.J(2) is the section corresponding to the case 3.I(sl) (see above) in which it can be seen that

$$\overline{a,b,c} < \overline{a',b',c'}$$

because of the angle in the middle of each side. Since zl = 3z2 Result 1 is obtained again for a side and Result 2 for the entire outline of the thread. In this close-up diagram the angle α can be seen resulting from the application of Procedure 1.

3.J(3) is the section corresponding to case 3.I(s2) in which it can be seen that

$$\overline{a,b,c} < \overline{a',b',c'} < \overline{a'',b'',c''}$$

because of the angles of secondary order; since zl = 3z2 = 9z3 there clearly follows Result 3. If only one side of the thread has had both Procedure 1 and Procedure 2 applied , the percentage increase in the surface area is 38.88...% (Result 4).

In principle there is nothing to stop Procedure 1 being applied a third time, and again and again getting closer and closer to the fractional shape called the "Koch snowflake"; for example applying again Procedure 1 to each of the 32 segments (taking into account both sides of the thread) 128 segments would be obtained, each one with a length of $1/27^{th}$ of the original side, with a given percentage increase of 100 (128/54-1) = 137% (Result 5). This surprising result means that, in other words, by applying the Procedure 1 a third time the area of the thread more than doubles. It can certainly be assumed that there is physical limit to the practicality of multiple applications of Procedure 1; nevertheless such a limit would still allow a reasonable number of repeats of the procedure. A typical implant screw has a thread with sides of around 0.45 mm, and these sides can be assumed for the sake of simplicity to be in a straight line; therefore in the first application of Procedure 1 segments of 0.15 mm would be obtained, in the second application around 0.05, in the third around 0.017, that is 17 micrometers, or microns; this is the same as the thickness of a thin hair, therefore well within the bounds of today's technology.

In the following table can be seen the results obtained if Procedure 1 is repeatedly applied to one or more of the sides of the thread:

Repeats	Segments per side of the thread	Length of the segment	Modifications on 1 side of the thread		Modifications on 2 sides of the thread.	
			Length of outline of thread	Perc. Incr. Area of the thread	Length of outline of thread	Perc.Incr. Area of the thread
0	1	0,45 mm	0,9 mm	0%	0,9 mm	0%
1	4	0,15 mm	1,05 mm	16,66%	1,2 mm	33,3%
2	16	0,05 mm	1,25 mm	38,88%	1,6 mm	77,7%
3	64	0,0166mm	1,516 mm	61,66%	2,13 mm	136,6%
4	256	5,55 μm	1.872 mm	108%	2,84 mm	215,5%
5	1024	1,85 μm	2,346 mm	160,7%	3,78 mm	321%

Table 1

As can be seen, after 5 repeats the area of the thread would be more than quadrupled, being in the order of a micrometer in size (a thousand times bigger than a nanometre); nevertheless the engineering of what has been proposed in this description will be limited to repeat 3 (around the diameter of an osteoblast) or repeat 4 (around the diameter of a red corpuscle).

The incision in this invention can take the form of isolated hollowing out in whatever shape or profile as shown in Figs. 4.M and 4.N, insets (5) and (6).

Protruding elements of varying shape, either isolated or joined up continuously, can be added afterwards, as can be seen in 2.E1(4), 2.E2(4), 2.E3a, 2.E3b, 2.F1(5), 2.F2a(5), 2.F2b(5), 4.N(4).

Another problem that could occur with regard to the strength or resilience of the screw, overall or in parts, is that the presence of these notches could weaken the screw or the shaft of the screw; in such case this invention provides for the angles to be rounded off in any section so that the forces are more evenly distributed, as illustrated in Fig. 3.L.

When the screw is fitted into its base, where previously there was a homogeneous tissue now there is a hollow with more or less regular walls, which follow the shape of the screw fairly closely.

As described above, it is of extreme importance to have as big a surface as possible for the wound chambers; an increase in this surface (requirement B) can be obtained for example by using a drill with a bigger diameter. In this case only the distal part of the thread is in contact with the bone, whilst the uncovered part of the shaft and the proximal part of the thread form part of the "chambers". The main problem with this method is that naturally what is obtained is at the expense of primary stability (requirement A) since the screw-bone contact area is reduced.

This invention has a possible solution to this problem, introducing tapping elements onto the surface of the thread and/or the uncovered parts of the shaft, theoretically at any point on the surface.

Such elements are able to cut into the bone surrounding the screw during fitting of the implant, in this way increasing the hollow volume and the area available in the chambers where new bone can be formed.

These can be placed on one or both surfaces of the thread, as illustrated in Fig. 1.B (one side) and 2.C (both sides); they can be single or multiple, and also of different sizes.

An example of a series of three tapping devices in a row with increasing sizes is in Fig. 1.B, whose sections can be seen 1.B(s1), 1.B(s2), 1.B(s3).

Another example (more than one row of tapping devices on the same side) is that of Fig. 2.D (shown in section in Fig.2.D1).

The tapping devices can also be on the shaft, as shown in Fig.4.N, detail (3).

If the incisions made on the implant described in paragraph (1), are carried out as illustrated in Fig.3.H2 – in which the incision reaches the apex of the screw, then they contribute to the increase in primary stability, in that the already existing contact surface between the implant and the bone is increased by the percentages shown in Table 1. The section is shown in Fig. 3H4, in which can be seen the thread (grey) and the bone (squared area).

This is also visible in Fig. 4.Oδ.

If the incisions made on the implant are carried out as shown in Fig.3.H1 (in section 3.H3) – in which the incision does not reach the apex of the screw – then they contribute to an increase in requirement B.

The protruding elements such as those shown as an example in Figs. 2.E1(4), 2.E2(4), 2.E3a, 2.E3b, 2.F1(5), 2.F2a(5), 2.F2b(5), 4.N(4) can contribute to the increase in the area of requirement B.

The incisions made into the bone by the tapping elements protruding from the implant , as described in paragraph (2) also contribute to the increase in the area of requirement B.

The increased space in the chambers produced by the methods described above are illustrated in Fig. 4Oγ.

The present invention has been described for illustrative but not limitative purposes, according to its preferred embodiments, but it is to be understood that modifications and/or changes can be introduced by those skilled in the art without departing from the relevant scope as defined in the enclosed claims.

CLAIMS

1) Bone implant screw with increased bone-implant interface, characterised in that it has at least a side of the thread profiled.

2) Screw according to claim 1, characterised in that said profiling is on both sides of the thread.

3) Screw according to one or more of the previous claims, characterised in that said profiling is also provided on the shaft of the screw.

4) Screw according to one or more of the previous claims, characterised in that said profiling is comprised of elements that protrude from the thread or from the shaft or from any part of the screw.

5) Screw according to one or more of the previous claims, characterised in that said profiling is comprised of elements, which are cut into the thread or shaft or any part of the screw.

6) Screw according to one or more of the previous claims, characterised in that each of the elements of said profiling can have any section.

7) Screw according to one or more of the preceding claims, characterised in that each of the elements of said profiling a fractal shape defined as “Koch's curves” and its variants or approximations.

8) Screw according to claim 4, characterised in that each of said protruding elements of the profiling is able to produce in the osseous tissue surrounding the implant incisions of any shape, section or size.

9) Screw according to claim 8, characterised in that protruding elements referred act on their own.

10) Screw according to claim 8, characterised in that protruding elements can act together each other.

11) Screw according to one or more of the previous claims, characterised in that each one of the profiling elements can follow any path, parallel or not to the edge of the thread.

12) Screw according to one or more of the previous claims, characterised in that each one of the profiling elements can be continuous or at intervals.

13) Screw according to one or more of the previous claims, characterised in that each one of the profiling elements can have the same or varying dimensions.

14) Screw according to one or more of the previous claims, characterised in that each one of the profiling elements can assume the form of an isolated indent of any section, profile or depth.

15) Screw according to one or more of the previous claims, characterised in that each one of the profiling elements can also assume the form of isolated indents of any section , protruding profile or height from the flat part of the thread or the shaft or any other part of the screw.

16) Screw according to one or more of the previous claims, characterised in that the angle or angles determined by or in the profiling and/or by or in its individual elements can be of any size.

17) Screw according to one or more of the previous claims, characterised in that the profiling and/or its individual elements is carried out at the same time as the screw is made or afterwards by whatever method or technique, in one way or in combination with others, such as by fusing, or extrusion, incision, machining or other method.

18) Screw according to one or more of the previous claims, characterised in that all angles, or some of them, can be realised by rounded parts.

19) Screw according to one or more of the previous claims, characterised in that the profile in a section of the thread is determined by parts that are in a straight line or curved or a combination of parts in a straight line or curved with a curve that is constant or variable.

20) Screw according to one or more of the previous claims, characterised in that it is cylindrical or conical or partly cylindrical and partly conical at the same time and/or of any shape.

21) Screw according to one or more of the previous claims, characterised in that it has in its coronal part any type of platform.

22) Screw according to one or more of the previous claims, characterised in that it has a thread with a spiral that is either self threading or not self threading.

23) Screw according to one or more of the previous claims, characterised in that it, in relation to its prosthetic connection, connected either internally or externally, hexagonal, stellar, or conical, or any other type of connection.

24) Screw according to one or more of the previous claims, characterised in that the fractal surface is machined, turned, treated and/or treated with all known types of chemical-physical processes.

25) Screw according to one or more of the previous claims, characterised in that the fractal surface is treated with nanostructure.

26) Screw according to one or more of the previous claims, characterised in that it is realised by any material, or combination of materials, both as far as the screw as a whole is concerned and as far as part of the same are concerned, such as rod, thread, head.

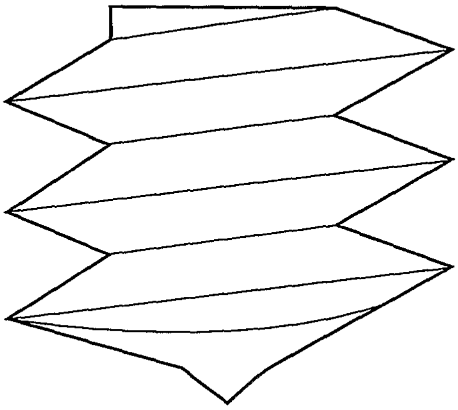


Fig. 1A

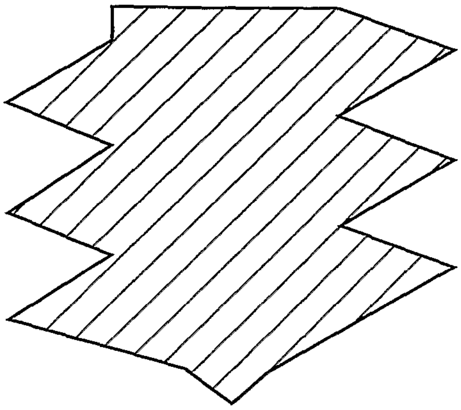


Fig. 1A s

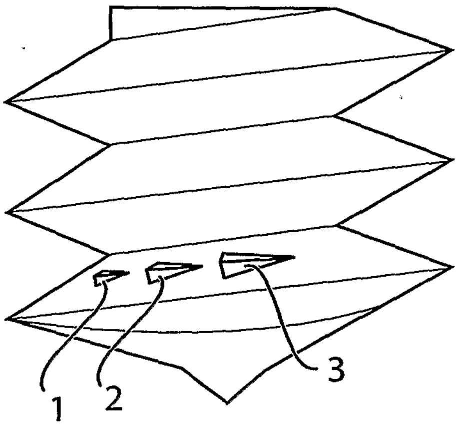


Fig. 1B

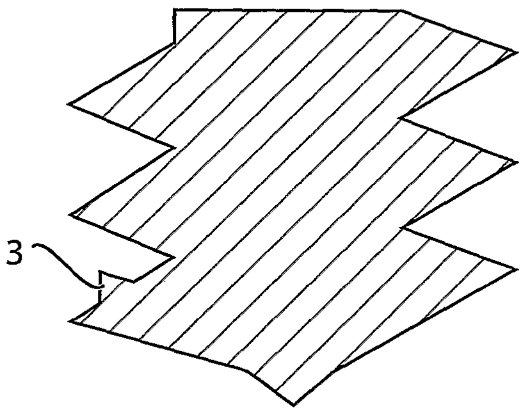


Fig. 1B(s3)

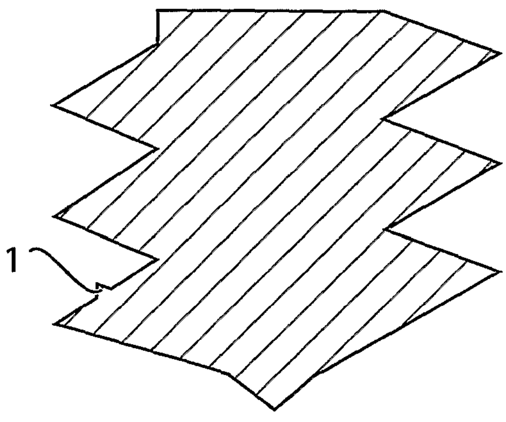


Fig. 1B(s1)

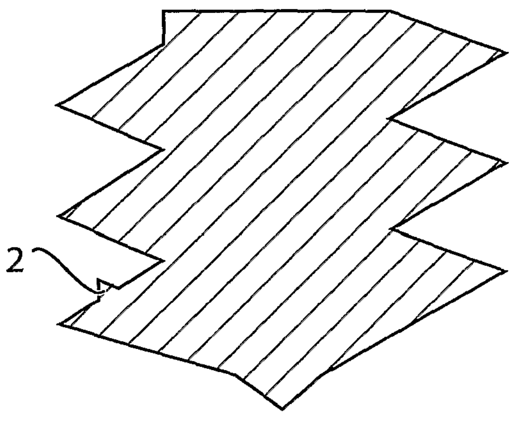


Fig. 1B(s2)

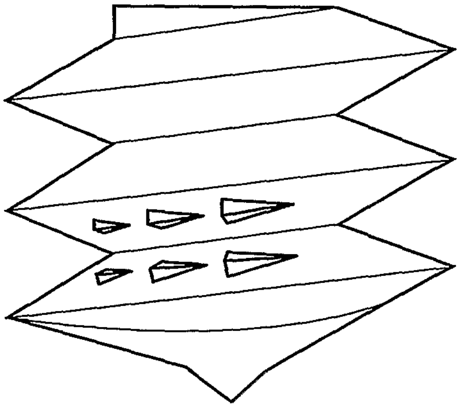


Fig. 2C

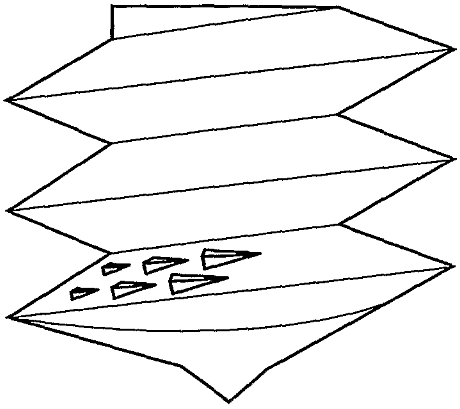


Fig. 2D

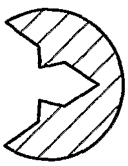


Fig. $2C_1$

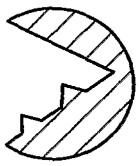


Fig. $2D_1$

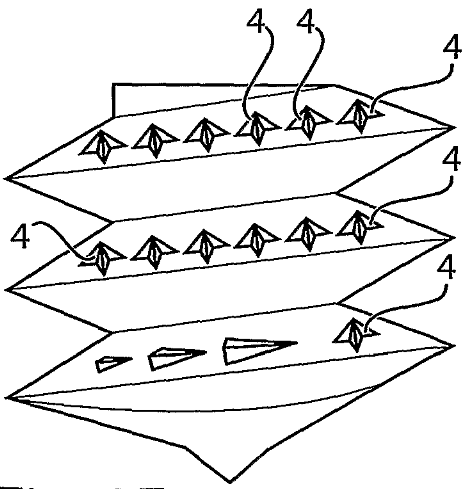


Fig. 2E1

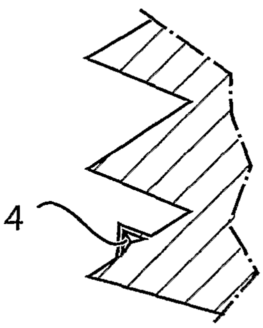


Fig. 2E2

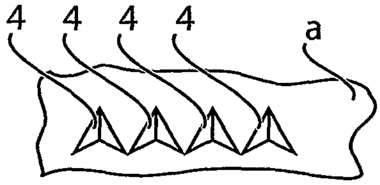


Fig. 2E3a

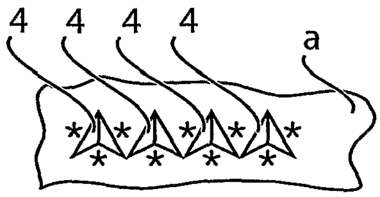


Fig. 2E3b

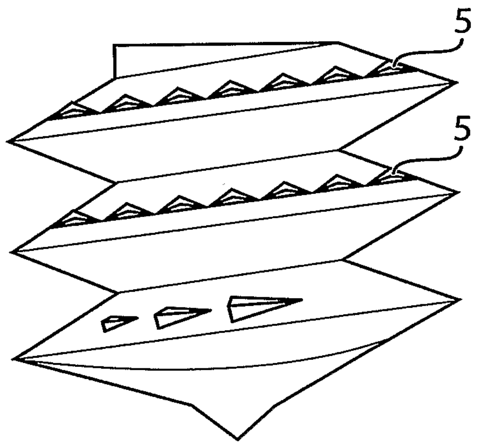


Fig. 2F1

4

Fig. 2F2a

Fig. 2F2b

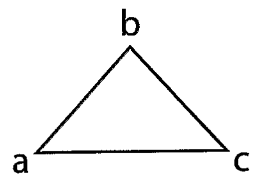


Fig. 2G1

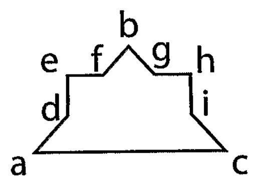


Fig. 2G3

G

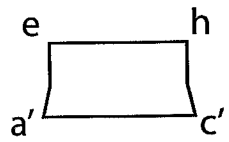


Fig. 2G2

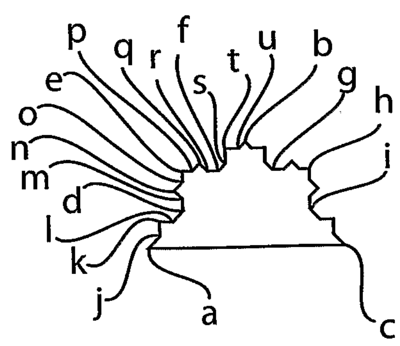


Fig. 2G4

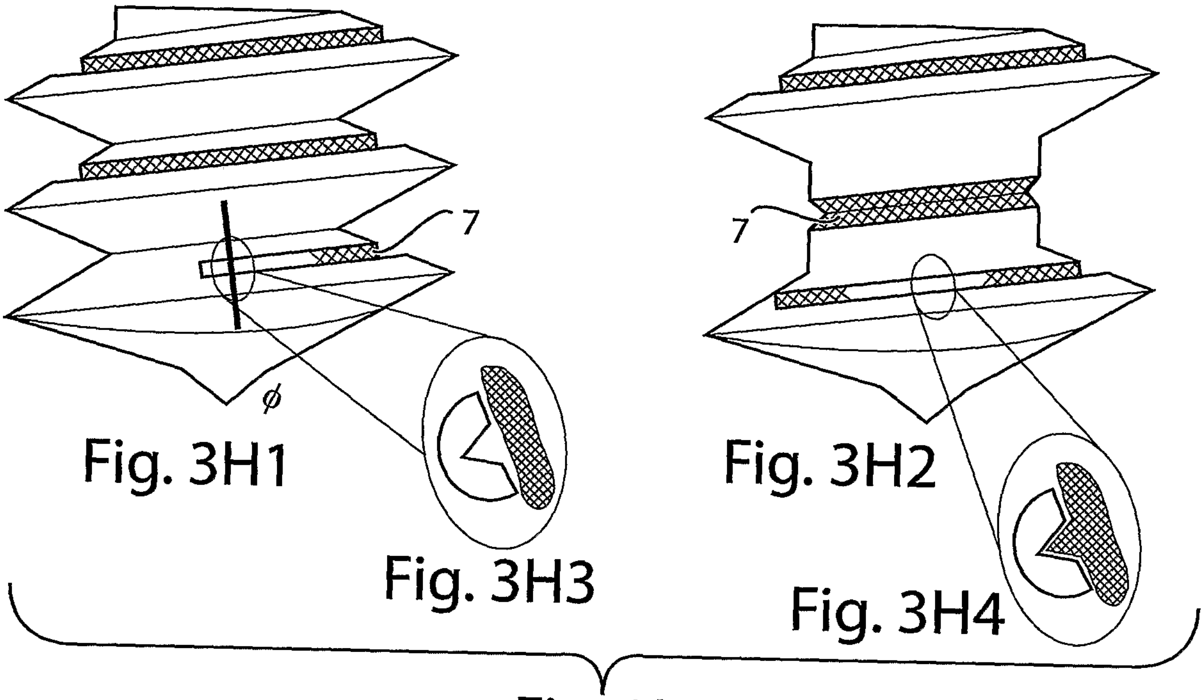


Fig. 3H

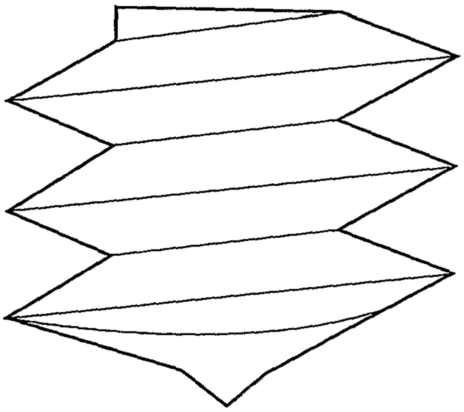


Fig. 3A

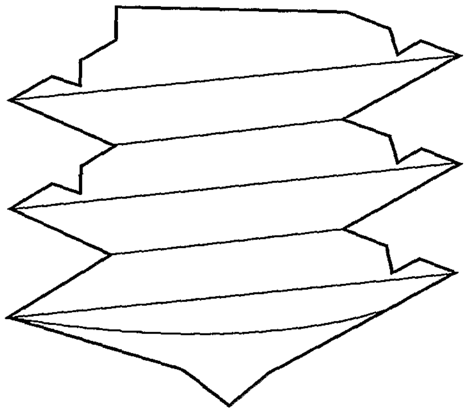


Fig. 3I(s0)

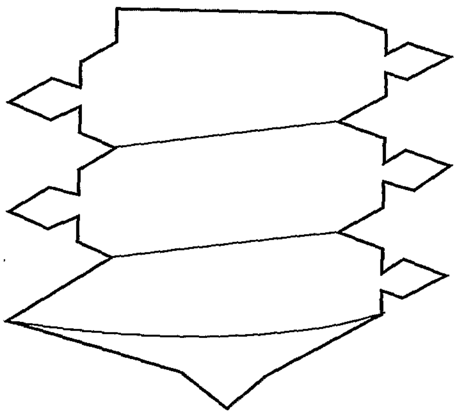


Fig. 3I(s1)

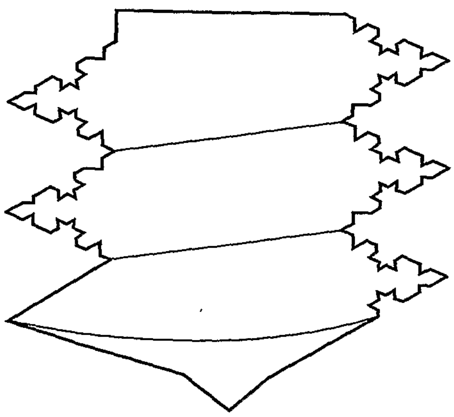


Fig. 3I(s2)

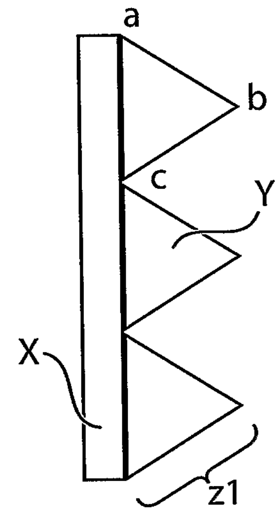
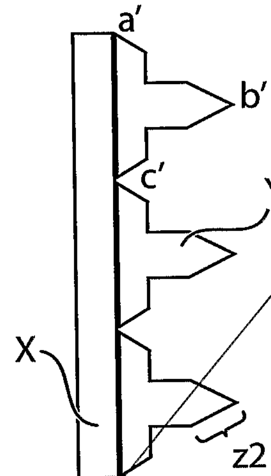


Fig. 3J(1)



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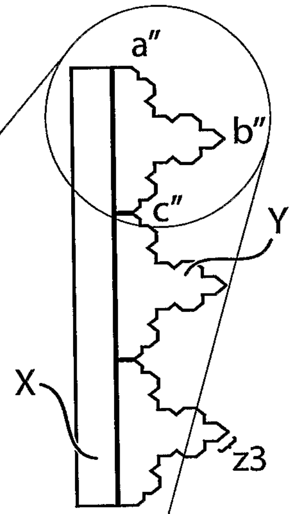

Fig. 3J(3)

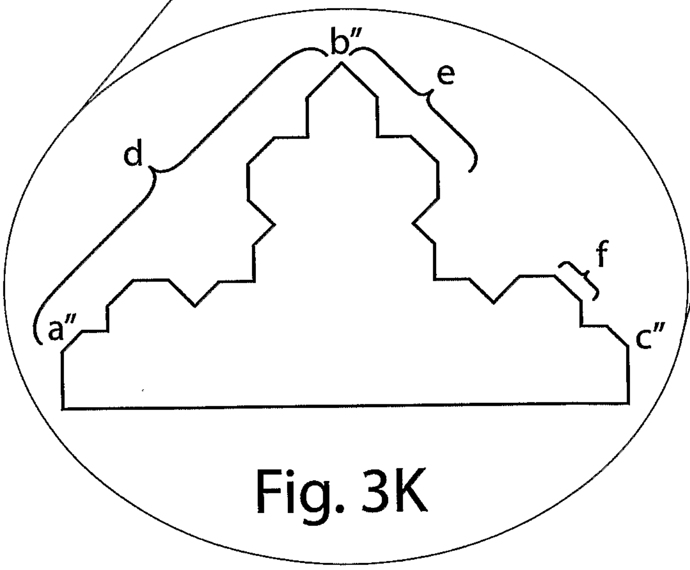

Fig. 3K

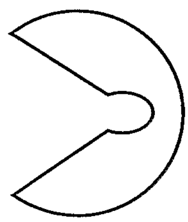

Fig. 3L

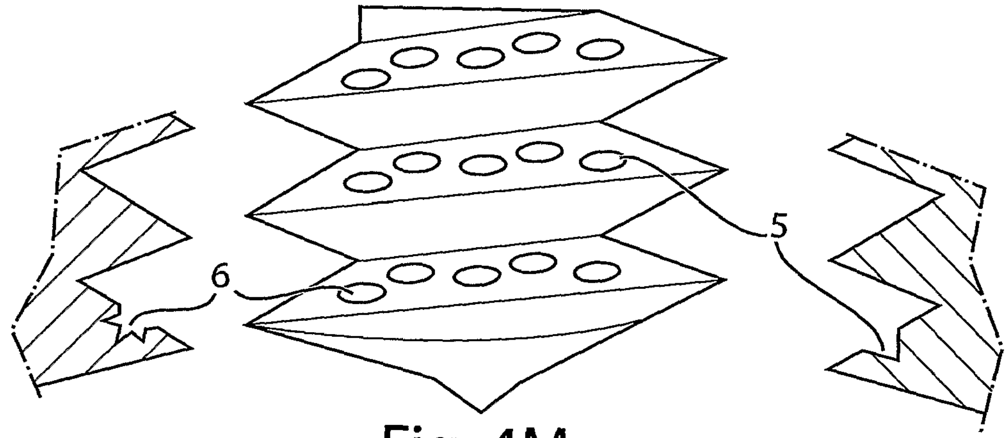

Fig. 4M

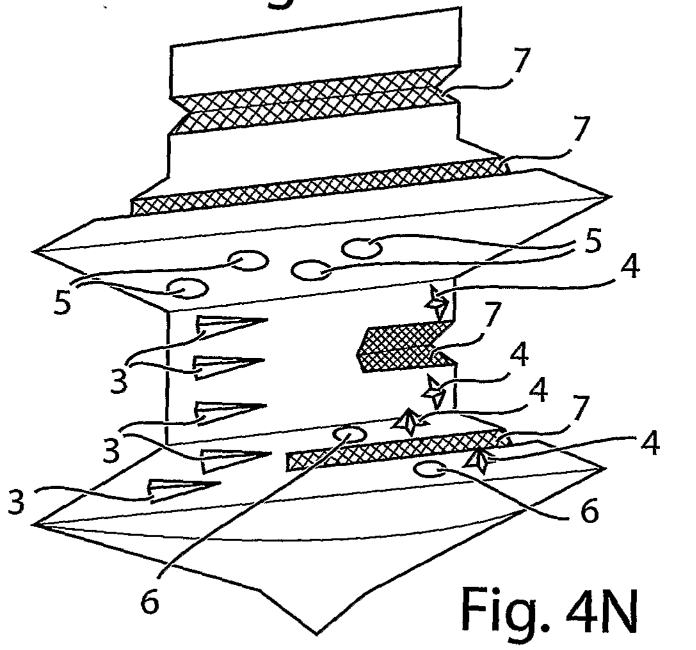

Fig. 4N

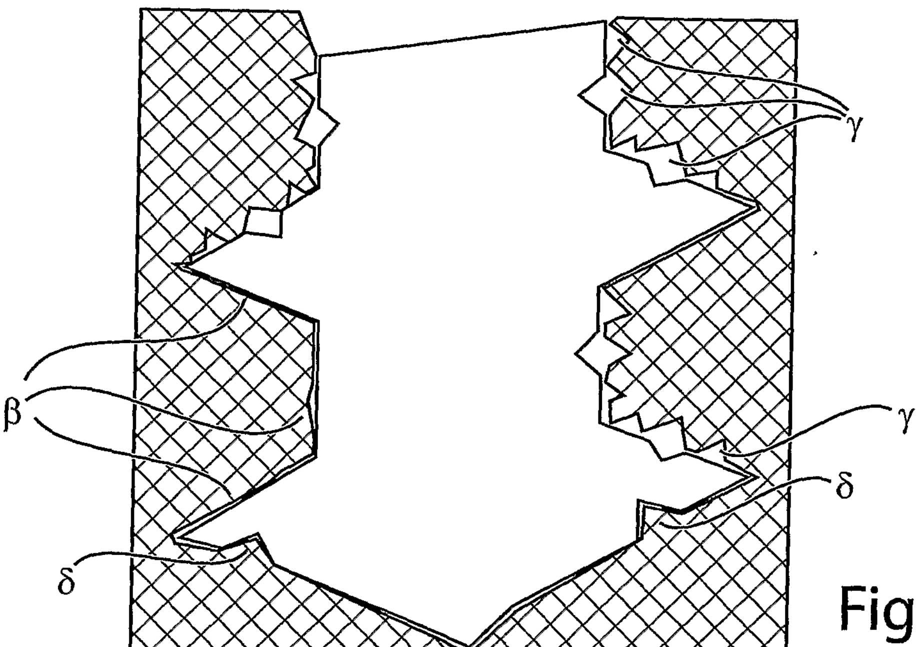

Fig. 4O