~~CLAIMS~~
Claims

1. Disgregating device (10) ~~of~~for disgregating biological material, in particular for the preparation of cell suspensions or tissue micrografts or microfragments of tissue, comprising:

- a hollow outer body (11), defining an inner chamber (12);

- a perforated plate or disgregating grid (13), fixed, having a plurality of microholes (13a) provided with sharp edges, said disgregating grid being housed transversely in said inner chamber (12) so as to define an upper loading chamber (12a) apt to be loaded with the biological material to be disgregated (MB) and a lower collecting chamber (12b) apt to collect the biological material, once disgregated (MB'); and

- a bladed rotor (14), rotating in said inner chamber (12), said bladed rotor (14) being apt to co-operate, rotating, with said disgregating grid (13), fixed, so as to feed and bring the biological material (MB), contained in the upper loading chamber (12a), into contact and to co-operate with the microholes (13a), with sharp edges, of said disgregating grid (13), and therefore cause the disgregation of the biological material (MB) while it passes through said microholes (13a);

characterised in that the microholes (13a) of said perforated disgregating grid (13) have dimensions or a diameter (D) of between 70 and 80 μm, and more preferably have dimensions or a diameter (D) of about 75 μm,
in that the microholes (13a) of said disgregating grid (13) are formed by means of a process of manufacturing by moulding of the die-punch (M, P) type, using a moulding punch (P~~), which can be selected from between a punch of the conical type or~~) of the polygonal-based pyramid-shaped type, ~~and~~

in that said moulding punch (P) and the corresponding die (M) are configured in such a way that each of said microholes (13a) is obtained through breakage and tearing of the material of a metal sheet (N) and has ~~a~~an irregular sharp edge (B), through the effect of this breakage or tearing, ~~in particular~~ defining a plurality of sharp tips,
and
in that said outer body (11) defines a through hole (11c), substantially vertical, which extends between an upper edge of said outer body (11) and the base of said collecting chamber (12b), wherein said through hole (11c) has the function of allowing the extraction of the disgregated biological material (MB'), accumulated in said collecting chamber (12b),
whereby said disgregating device (10) is apt to prepare cell suspensions and set up tissue micrografts that preserve intact the characteristics and cell viability of the original biological material, not disgregated, thereby avoiding the use of chemical reagents in the preparation of these cell suspensions and in the setting-up of these tissue micrografts. ~~2. Disgregating device (10) of biological material, in particular for the preparation of cell suspensions or of tissue micrografts or of microfragments of tissue, comprising:~~

~~a hollow outer body (11), defining an inner chamber (12);~~

~~a perforated plate or disgregating grid (13), fixed, having a plurality of microholes (13a) provided with respective sharp edges, said disgregating grid being housed transversely in said inner chamber (12) so as to define an upper loading chamber (12a) apt to be loaded with the biological~~

material to be disgregated (MB) and a lower collecting chamber (12b) apt to collect the biological material, once disgregated (MB'); and

a bladed rotor (14), rotating in said inner chamber (12), said bladed rotor (14) being apt to co-operate, rotating, with said disgregating grid (13), fixed, so as to feed and bring the biological material (MB), contained in the upper loading chamber (12a), into contact and to co-operate with the microholes (13a), with sharp edges, of said disgregating grid (13), and therefore cause the disgregation of the biological material (MB) while it passes through said microholes (13a);

characterised in that the microholes (13a) of said perforated disgregating grid (13) have dimensions or a diameter (D) comprised between 70 and 80 μη, and more preferably have dimensions or a diameter (D) of about 75 μιη,

in that the microholes (13a) of said disgregating grid (13) are formed by means of a process of manufacturing by moulding of the die-punch (M, P) type, using a punch (P) and a die (M) apt to co-operate one with the other to deform a metal sheet ( );

in that said moulding punch (P) and said die (M) are configured in such a way as to deform and draw only the material of said metal sheet (N) without causing tears and/or breakages; and

in that the orifice of each one of said microholes (13a) and the respective sharp

edge (B) are obtained by perforating, by means of a source of laser light, the tip of the zone of material drawn by the action of the punch (P) and of the die (M),

whereby said disgregating device (10) is apt to prepare cell suspensions and set up tissue micrografts that preserve intact the characteristics and cell viability of the original biological material, not disgregated, thereby avoiding the use of chemical reagents in the preparation of these cell suspensions and in the setting-up of these tissue micrografts. 3.

2. Disgregating device (10) of biological material according to claim 1 or 2, wherein said bladed rotor (14) is constituted by:

- a shaft (14a), arranged in the vertical direction;

- a distributing blade (14b), associated with a lower end of said vertical shaft (14a) and exhibiting a curved helical shape; and

- a lower scraper (14c), also associated with the lower end of said vertical shaft (14a),

wherein the disgregating grid (13), fixed, is interposed between said helical distributing blade (14b) and said lower scraper (14c), both associated with the lower end of said vertical shaft (14a), whereby said bladed rotor (14) is suitable to co-operate, by rotating, through its helical distributing blade (14b) and its lower scraper (14c), respectively with an upper face of said disgregating grid (13), turned towards said upper loading chamber (12a), in order to distribute and bring the biological material (MB) to be disgregated into contact with the microholes (13a) of the disgregating grid (13), and with a lower face, of said disgregating grid (13), turned towards said collecting chamber (12b), in order to scrape the disgregated biological material (MB') that comes out of the microholes (13a) of said disgregating grid (13) and discharge (f2) it in said collecting chamber (12b).

4. Disgregating device (10) of biological material according to any one of the preceding claims, wherein said outer body (11) defines a through hole (11c), substantially vertical, which extends

between an upper edge of said outer body (11) and the base of said collecting chamber (12b), wherein said through hole (11c) has the function of

allowing the extraction of the disgregated biological material (MB'), accumulated in said collecting chamber (12b).

5. Disgregating device (10) of biological material

3. Disgregating device (10) according to any one of the preceding claims, wherein said outer body (11) is associated with a secondary internal body (16), defining said upper loading chamber (12a), and is constituted by an upper portion (11a) defining a seat (1 F11') which houses said secondary internal body (16) and a lower portion (I ib11b) that defines said lower collecting chamber (12b),

wherein said disgregating grid (13) is interposed between said secondary internal body (16), housed in said seat (1 F11') defined by the upper portion (1 Ia11a) of said outer body (11), and the lower portion (I ib11b), defining said lower collecting chamber (12b), of said outer body (11), and

wherein said secondary internal body (16) forms a support seat for rotatably supporting said bladed rotor (14), and in particular the respective shaft (14a), and is coupled to the upper portion (11a) of said outer body (11) so as not to rotate and thus avoid any rotation of the disgregating grid (13), interposed between said secondary internal body (16) and the lower portion (1 Ib11b) of said outer body (11), when said bladed rotor (14) rotates in said inner chamber (12) in order to cause the disgregation of the biological material (MB).

64. Disgregating device (10) of biological material according to any one of the preceding claims, wherein each microhole (13a) of said disgregating grid (13) is surmounted by a plurality of blades, and exhibits, in particular, a hexagonal shape, with six blades each one associated with a respective side of the hexagon.

75. Disgregating device (10) of biological material according to any one of the preceding claims, further comprising a cover (15), removable, for covering said upper loading chamber (12a), wherein said bladed rotor (14) extends through a hole (15a) formed in said cover (15), whereby said bladed rotor partially protrudes at a respective upper end from said cover (15) so as to allow the coupling of said bladed rotor (14) with suitable motor means apt to control its rotation in said inner chamber (12).

86. Disgregating device (10) of biological material according to any one of the preceding claims, as dependent on claim 32, wherein said scraper (14c) is formed by a plurality of blades, in the form of a peg, in particular two, opposite one to the other, which extend radially from the lower end of the shaft (14a) of said bladed rotor (14).

9.7. Disgregating device (10, 10-1; 10-2) according to any one of claims 1 to 6, wherein the disgregating device (10) comprises a magnetic element (MAG), constituted in particular by a permanent magnet, apt to attract with a pre-established load the helical blade (14b) of the bladed

rotor (14), in such a way as to control, in the use of the disgregating device (10), the pressure applied by the same bladed rotor (14b) on the disgregating grid (13).

8. Disgregating device (10, 10-1; 10-2) according to claim 7, wherein the magnetic element (MAG) is attached to the base of the tray or lower collecting chamber (12b) of the disgregating device (10).

9. Disgregating device (10, 10-1; 10-2) according to claim 8, wherein the magnetic element (MAG) is attached on the base of a seat (S) formed in an additional support base (BA) and having the function of receiving and housing during use the disgregating device (10).

10. Method for the manufacturing of a disgregating device (10) ~~of~~for disgregating biological material, of the type including at least one perforated plate or disgregating grid (13) having a plurality of sharp microholes (13a) through which the biological material is made to pass in order to be disgregated~~.~~

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wherein the method comprises a step of moulding in order to mould, by means of a mould (S) of the die-punch type, a metal leaf or strip (N), original, in particular of 316L stainless steel, in order to form in said metal leaf (N) the microholes (13a) of the disgregating grid (13);

wherein the die (M) and the punch (P) of the mould (S) are configured in such a way as to draw and tear, during said moulding phase, the metal leaf (N), so as to obtain through tearing and breakage of said metal leaf (N) the microholes (13a) of said disgregating grid (13);~~ and~~

~~wherein the microholes (13a) of the disgregating grid (13), obtained through the tearing of the original metal strip (N), have dimensions or a diameter (D) comprised between 70 and 80 μm, and more preferably have dimensions or a diameter (D) of about 75 μm.~~

~~10. Method for the manufacturing of a disgregating device according to claim 9~~
wherein the punch (P) of the mould (S) has a ~~pointed conical configuration suitable for forming said microholes (13) through tearing and breakage of the material of the original metal strip (N).~~

~~11. Method for the manufacturing of a disgregating device (10) of biological material according to claim 9 wherein the punch (P) of the mould (S) has a pointed~~ polygonal~~-based pyramid-shaped~~ configuration, for example with six sides, so that the microholes (13a) of said disgregating grid (13), obtained through tearing and breakage of the original metal strip (N), each have a jagged sharp edge with several tips, for example six, corresponding in number to that of the sides of the polygonal punch~~; and~~
~~wherein the microholes (13a) of the disgregating grid (13), obtained through the tearing of the original metal strip (N), have dimensions or a diameter (D) comprised between 70 and 80 μm, and more preferably have dimensions or a diameter (D) of about 75 μm~~.

~~12. Method for the manufacturing~~ 11. A combination of a disgregating device (10) ~~of biological material, of the type including at least one perforated plate or disgregating grid (13) having a plurality of sharp microholes (13a) through which the biological material is made to pass in order to be disgregated.~~

wherein the method comprises a step of moulding in order to mould, by means of a mould (S) of the die-punch type, a metal leaf or strip (N), original, in particular of 316L stainless steel, in order to form in said metal leaf (N) the microholes (13a) of the disgregating grid (13);

wherein the die (M) and the punch (P) of the mould (S) are configured in such a way as to only deform and draw, during said step of moulding, the original metal leaf (N), therefore without breaking it or tearing it, and

wherein the method comprises a further successive step of drilling in which the microholes (13a) are formed by means of a source of laser light in the central region of each zone, of the original metal tape (N), drawn during the preceding step of moulding.

13. Method for the preparation of a tissue micrograft or a cell suspension comprising the following steps:

providing a disgregating device (10) of biological material according to any one of claims 1 to 8;

loading the biological material (MB), in particular a fragment of tissue or a biopsy sample, in the upper loading chamber (12a) of said disgregating device (10);

activating said disgregating device (10); and

extracting the disgregated biological material (MB'), in the form of tissue micrograft or cell suspension, from the collecting chamber (12b) of the disgregating device (10).

14. Method according to claim 13, further comprising the step of loading, in the loading chamber (12a), a physiological solution apt to perform a lubricating action during the process of disgregation of the biological material (MB) and to operate as a means for recovering the disgregated biological material (MB').

15. Method for the preparation of a tissue micrograft according to claim 13 or 14, wherein the tissue micrograft, prepared with said method, is used in the field of aesthetic, cosmetic, plastic and dermatological treatments.

16. Method for the preparation of a tissue micrograft or a cell suspension according to claim 13 or 14 wherein the cell suspension is used in the veterinary field.

17. Method for the preparation of a cell suspension according to claim 13 or 14 wherein the cell suspension, prepared in accordance with said method, is used for purposes of research and of simple laboratory analysis without a direct therapeutic purpose.

18. Cell suspension (MB') or tissue micrograft obtainable by the method according to any one of claims 13 to 17.

19. Use of a device according to any one of claims 1 to 8 for the preparation of tissue micrografts and cell suspensions.

20. Disgregating device (10) according to any one of claims 1 to 86, for the preparation of microfragments of tissue, in combination with and an adapter (20) apt to connect the same device (10) to a usual surgical manipulator included in the supply of instruments and devices, sterile, normally present in the operating theatre.

21. Disgregating device (10) in12. A combination with said adapter (20), in accordance with claim 2011, wherein the adapter (20) has an elongated shape with one end (20a) apt to be connected

to a projecting shaft (14a) of said bladed rotor (14) and an opposite end (20b) apt to be connected to the surgical manipulator.

~~22. Use of a disgregating device of biological material according to any one of claims 1 to 8, in combination with an adapter (20) apt to connect the device to a surgical manipulator already present in the operating theatre.~~

~~23. Disgregating device (10, 10-1; 10-2) of biological material according to any one of claims 1 to 8, wherein the disgregating device (10) is associated with a magnetic element (MAG), constituted in particular by a permanent magnet, apt to attract with a pre-established load the helical blade (14b) of the bladed rotor (14), in such a way as to control, in the use of the disgregating device (10), the pressure applied by the same bladed rotor (14b) on the disgregating grid (13).~~

~~24. Disgregating device (10, 10-1 ; 10-2) of biological material according to claim 23, wherein the magnetic element (MAG) is attached to the base of the tray or lower collecting chamber (12b) of the disgregating device (10).~~

~~25. Disgregating device (10, 10-1 ; 10-2) of biological material according to claim 23, wherein the magnetic element (MAG) is attached on the base of a seat (S) formed in an additional support base (BA) and having the function of receiving and housing during use the disgregating device (10).~~