Claims

1. Disgregating device (10) 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) of the polygonal-based pyramid-shaped type,
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 an irregular sharp edge (B), through the effect of this breakage or tearing, 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) according to claim 1, 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).

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 (11') which houses said secondary internal body (16) and a lower portion (11b) that defines said lower collecting chamber (12b),
wherein said disgregating grid (13) is interposed between said secondary internal body (16), housed in said seat (11') defined by the upper portion (11a) of said outer body (11), and the lower portion (11b), 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 (11b) 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).

4. Disgregating device (10) 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.

5. Disgregating device (10) 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).

6. Disgregating device (10) according to claim 2, 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).

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) 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,
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);
wherein the punch (P) of the mould (S) has a 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.

11. A combination of a disgregating device (10) according to any one of claims 1 to 6, for the preparation of microfragments of tissue 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.

12. A combination in accordance with claim 11, 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.