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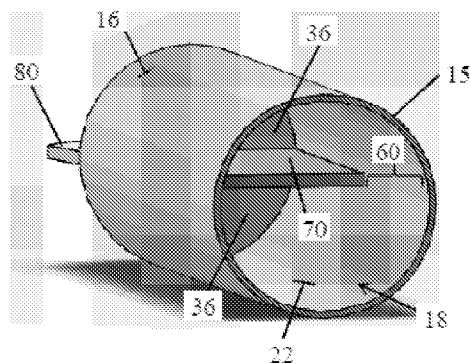


FIG. 6A

(57) Abstract: The subject invention provides devices and methods for alleviating discomfort associated with neuroma formation. The devices and methods of the invention effectively use the body's natural response of reconstructing implanted biomaterials to minimize the size of, isolate, and protect a neuroma. In preferred embodiments, the subject device is a cylindrical cap, wherein the internal chamber of the cylindrical cap physically partitions the nerve to enable an arrangement of nerve fibers (as opposed to haphazardly arranged nerve fibers often produced in neuromas). Tabs arranged on the outside of the cap can be used to manipulate the cap into place on a nerve. The open end can also be configured with flaps that can be used to widen the open end for easier insertion of the nerve into the cap. In addition, the cap's material remodels into a tissue cushion after implantation, which protects the neuroma from being stimulated and inducing pain.



AMENDED CLAIMS
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CLAIMS

We claim:

1. A sterile cap, adapted to receive a terminal nerve end, the cap comprising:
 - an external body having a distal end, a proximal end with a single opening, and an internal chamber between the distal end and the proximal end, where the external body comprises a biomaterial that remodels around the terminal nerve end to form a tissue cushion; and
 - at least one divider within the internal chamber that subdivides at least a portion of the internal chamber, at the distal end, into two or more separate channels, where the at least one divider comprises a biomaterial that remodels around the separate channels to form a tissue cushion between each separate channel;
 - a retaining cavity between the single opening at the proximal end and the at least one divider;
 - such that, when a terminal nerve end is positioned within the cap through the single opening, and nerve fibers of the terminal nerve end regenerate within the separate channels, one or more of the nerve fibers of the terminal nerve end will be isolated and protected from other of the nerve fibers of the terminal nerve end within the cap.
2. The cap according to claim 1, wherein the biomaterial is selected from the group consisting of: high density polyethylene (HDPE), polyethylene glycol (PEG) hydrogel, and purified proteins from human or sources.
3. The cap according to claim 1, wherein the biomaterial is selected from the group consisting of: small intestine submucosa (SIS), amnion, dermis, collagen and decellularized fascia.
4. (Cancelled)

5. The cap, according to claim 1, wherein the at least one divider comprises at least one of: panels, a spiral shaped wall, and concentric tubes.
6. The cap, according to claim 1, further comprising at least one tab extending from the external body.
7. The cap, according to claim 6, wherein the at least one tab extends from one or more of: a side of the external body, the distal end of the external body, and an edge of the single opening in the external body.
8. A sterile cap, adapted to receive a terminal nerve end, the cap comprising:
 - an external body having a distal end, a proximal end with a single opening, and an internal chamber between the distal end and the proximal end, where the external body comprises a biomaterial that remodels around the terminal nerve end to form a tissue cushion;
 - at least one divider within the internal chamber that subdivides at least a portion of the internal chamber, at the distal end, into two or more separate channels, where the at least one divider comprises a biomaterial that remodels around the separate channels to form a tissue cushion between each separate channel; and
 - at least one flap configured around the single opening of the external body, where the at least one flap forms a slot to increase the size of the single opening and wherein the at least one flap is adapted to be wrapped around the terminal nerve end to close the slot and reduce the size of the single opening around the terminal nerve end, wherein the at least one flap is formed by a slit in the proximal end of the external body that is integral with the single opening and advances partially towards the distal end along the external body of the cap,
 - such that, when a terminal nerve end is positioned within the cap through the slot and the single opening, and nerve fibers of the terminal nerve end regenerate within the separate channels, one or more of the nerve fibers of the terminal nerve end will be isolated and protected from other of the nerve fibers of the terminal nerve end within the cap.

9. The cap, according to claim 8, further comprising a retaining cavity between the single opening at the proximal end and the at least one divider.
10. The cap, according to claim 9, wherein the at least one divider comprises at least one of: panels, a spiral shaped wall, and concentric tubes.
11. The cap, according to claim 8, further comprising at least one tab extending from the external body.
12. The cap, according to claim 11, wherein the at least one tab extends from one or more of: a side of the external body, the distal end of the external body, and an edge of the single opening in the external body.
13. A method for covering a terminal nerve end comprising:
 - positioning a cap, according to claim 1, at or near to a terminal nerve,
 - inserting the terminal nerve end through the single opening into the internal chamber, and
 - securing the cap to the terminal nerve end.
14. The method, according to claim 13, further comprising positioning the terminal nerve end in proximity to the dividers..
15. The method, according to claim 14, wherein the cap further comprises a retaining cavity between the at least one divider and the single opening and the method further comprises positioning the terminal nerve end in the retaining cavity.
16. The method, according to claim 13, wherein the cap further comprises one or more tabs and the method comprises utilizing the one or more tabs to manipulate the cap onto the terminal nerve end.

17. The method, according to claim 16, further comprising attaching the one or more tabs to other structures to secure the position of the cap and terminal nerve end therein.

18. The method according to claim 13, wherein the cap further comprises at least one flap configured around the single opening that forms a slot to increase the size of the single opening and the method further comprises spreading the flap and inserting the terminal nerve end through the slot into the internal chamber

19. The method, according to claim 18, wherein the slot opens proximal to the at least one divider and the method comprises inserting the terminal nerve end through the slot so that the terminal nerve end is proximal to the dividers.

20. The method, according to claim 18, wherein the at least one flap is formed by a slit that extends from the single opening towards the distal end of the external body of the cap.