[0025] In some embodiments of the injector, the syringe may have a plunger for dispensing the therapeutic product from the syringe and through the needle and further comprising a plunger drive for driving the plunger through the syringe to dispense the therapeutic product from the syringe and through the needle, the plunger drive having one of a motor drive element, a spring drive element, a hydraulic drive element, or any combination thereof.

[0026] In some embodiments of the injector, the plunger drive may be activated by pressing a button feature on the cover.

[0027] In some embodiments of the injector, the plunger drive may be activated by pressing the cover toward the base.

[0028] Some embodiments of the injector may further comprise a carrier drive for moving the carrier between the first and second positions, the carrier drive having one of a motor drive element, a spring drive element, a hydraulic drive element, ~~of~~ or any combination thereof.

[0029] In some embodiments of the injector, the carrier drive may be activated by pressing a button feature on the cover.

[0030] In some embodiments of the injector, the carrier drive may be activated by pressing the cover toward the base.

[0031] In some embodiments of the injector, the carrier drive may be disposed at an acute angle relative to the base.

[0032] Some embodiments of the injector may further comprise a needle guide for bending the needle into the injection chamber.

[0033] Some embodiments of the injector may further comprise a heating element disposed adjacent to the carrier for heating the therapeutic product contained in the syringe.

[0034] In some embodiments of the injector, the heating element may comprise an exothermic heating element.

[0035] In some embodiments, the injector may further comprise an indicator to communicate that the injector and therapeutic product are at the optimal operating condition.

[0036] In some embodiments of the injector, the syringe may have a plunger for dispensing the therapeutic product from the syringe and through the needle and may further comprise a plunger drive for driving the plunger through the syringe to dispense the therapeutic product from the syringe and through the needle and a carrier drive for moving the carrier between the first and second positions, each of the plunger and carrier drives having one of a motor drive element, a spring drive element, a hydraulic drive element, ~~and~~ or combination thereof.

[0037] In some embodiments of the injector, at least one of the plunger and carrier drives may be activated by pressing the cover toward the base or by pressing a button feature on the cover.

[0038] In some embodiments of the injector, the syringe may comprise at least two barrels coupled to the needle, each barrel containing a therapeutic product.

[0039] Some embodiments of the injector may further comprise at least a second carrier.

position. When the palm-button 112 and cover 110 are pressed down toward the base 102 to activate an injection cycle of the AI device 100, the carrier trigger 138T may pivot and cause the carrier trigger rails 138TR to disengage the insertion spring holds 138 SH from the compressed insertion springs 138IS. Once disengaged, the insertion springs 138IS may expand and engage the rear abutment surfaces 134TR of the syringe carrier drive tabs 134T and move the syringe carrier 134 from the needle retracted position to the needle inserted position. As the syringe carrier 134 moves to the needle inserted position, the retraction springs 138RS, which are generally uncompressed, may engage the front abutment surfaces 134TF of the carrier drive tabs 134T (in the needle retracted position), and compress via the spring forces exerted on rear abutment surfaces 134TR of the tabs 134T by the expanding insertion springs 138IS. The insertion springs 138IS may have a higher spring rate than the retraction springs 138RS so that they can compress the retraction springs 138RS and move the syringe carrier 134 to the needle inserted position.

[0070] The retraction spring holds 138RH may be selectively positioned on the carrier trigger rails 138TR so that as the palm-button 112 and cover 110 are pressed further down toward the base 102 and the syringe carrier 134 reaches the needle inserted position, the pivoting carrier trigger 138T causes the carrier trigger rails 138TR to engage the retraction spring holds 138RH with the compressed retraction springs 138 RS to hold them in the compressed state until the plunger drive 140 completes drug extrusion. Once drug extrusion is completed and as the palm-button 112 and cover 110 are pressed completely down toward the base 102, the pivoting carrier trigger 138T may cause the carrier trigger rails 138TR to disengage the retraction spring holds 138RH from the

compressed retraction springs 138RS. Once disengaged, the retraction springs 138RS may expand and engage the front abutment surfaces ~~134TR~~ 134TF of the syringe carrier drive tabs 134T and move the syringe carrier 134 from the needle inserted position back to the needle retracted position.

[0071] Referring still to FIG. 5, the plunger drive 140 may push the plunger rod 136P and the stopper 136S, which is operatively connected to the forward end of the plunger rod 136P, down through the syringe barrel 136B to extrude the drug contained within the barrel 136B through the needle 136N and into the user during the drug extrusion process of the AI injection cycle. As shown, some embodiments of the plunger drive 140 may include a pivoting plunger trigger 140T, a plunger hold 140H, and a plunger drive spring 140S. The plunger hold 140 H has one end operatively connected to the plunger trigger 140T and the other end engaged with the plunger rod 136P. The plunger drive spring 140 may be operatively connected to the plunger rod 136P so that in the initial needle retracted position, it is held in a compressed state. When the palm-button 112/cover 110 are pressed down toward the base 102 to activate an injection cycle of the AI device 100, the plunger trigger 140T (as well as the carrier trigger 138T) starts to pivot. When the syringe carrier 134 reaches the needle inserted position which causes the needle 136N to penetrate the user's skin, the pivoting plunger trigger 140T causes the plunger hold 140H to release the plunger rod 136P. Once released, the compressed plunger drive spring 140S expands and pushes the plunger rod 136P and the stopper 136S down through the syringe barrel 136B, thereby extruding the drug contained within the barrel 136B through the needle 136N into the user.

[0072] Referring again to FIG. 4, in one embodiment the releasable substrate 106 which covers the flexible layer 104 of the base 102 may be constructed as a needle shield remover by providing barb-style or like gripping elements or projections 106G that extend up from the top surface 106T of the substrate 106, into the injection chambers 128 and grip the needle shields 136NS (FIG. 5). When the user is ready to use the AI device 100, he or she simply peels the releasable substrate 106 off the flexible layer 104 to remove all the needle shields 136NS covering the needles 136 N at essentially the same time. To facilitate removal of the releasable substrate 106, a pull tab structure 106PT may be attached to the bottom surface 106B of the substrate 106. The pull tab structure 106PT may include opposing portions 106OP that each has a thickness that gradually increases moving from a center 106C of the pull tab structure 106 PT. The pull tab structure 106PT may also be provided with two parallel lines of weakness 106L located adjacent the center 106C thereof that allow the two thick outer opposing portions 106OP of the pull tab structure 106PT to be folded together to form a pull tab (not shown) which can be easily gripped and pulled with the fingers to remove the peelable substrate 106 from the flexible layer 104 of the base 102.

[0073] Other embodiments of the AI device may have various other types of carrier and/or plunger drive mechanisms. Some of these mechanisms may utilize stored energy in any known form including, without limitation, electrical, gas pressure, gas releasing, or any combination thereof. The stored energy can be transmitted by corresponding conventional transmission mechanisms, e.g. electromechanical, such as electric motors or solenoids, hydraulic, pneumatic, gears, rods, and the like. The drive control and

activation unit may be provided for activating and sequencing the drive mechanisms and may comprise any well know type of a releasable lock arrangements, electronic controllers, combinations thereof, and the like.

[0074] The syringe(s) or other primary container(s) of the AI device may be filled for treatment or be prefilled with a pharmaceutical product, such as an erythropoiesis stimulating agent (ESA), which may be in a liquid or a lyophilized form. An ESA can be an erythropoiesis stimulating protein. As used herein, "erythropoiesis stimulating protein" means any protein that directly or indirectly causes activation of the erythropoietin receptor, for example, by binding to and causing dimerization of the receptor. Erythropoiesis stimulating proteins comprise erythropoietin and variants, analogs, or derivatives thereof that bind to and activate erythropoietin receptor; antibodies that bind to erythropoietin receptor and activate the receptor; or peptides that bind to and activate erythropoietin receptor. Erythropoiesis stimulating proteins comprise, but are not limited to, epoetin alfa, epoetin beta, epoetin delta, epoetin omega, epoetin iota, epoetin zeta, and analogs thereof, pegylated erythropoietin, carbamylated erythropoietin, mimetic peptides (comprising EMPl/Hematide), and mimetic antibodies. Exemplary erythropoiesis stimulating proteins comprise erythropoietin, darbepoetin, erythropoietin agonist variants, and peptides or antibodies that bind and activate erythropoietin receptor.

[0075] The term erythropoiesis stimulating protein comprises without limitation Epogen® (epoetin alfa), Aranesp® (darbepoetin alfa), Dynepo® (epoetin delta), Mircera® (~~methyoxy~~ methoxy polyethylene glycol-epoetin beta), Hematide™ (peginesatide),

2004/033651; WO 2004/035603; WO 2004/043382; WO 2004/101600; WO 2004/101606; WO 2004/101611; WO 2004/106373; WO 2004/018667; WO 2005/001025; WO 2005/001136; WO 2005/021579; WO 2005/025606; WO 2005/032460; WO 2005/051327; WO 2005/063808; WO 2005/063809; WO 2005/070451; WO 2005/081687; WO 2005/084711; WO 2005/103076; WO 2005/100403; WO 2005/092369; WO 2006/50959; WO 2006/02646; WO 2006/29094; and WO 2007/136752.

[0077] Alternatively, the syringe(s) or other primary container(s) of the AI device may also be filled for treatment or be prefilled with other products. Examples of other pharmaceutical products that may be used may comprise, but are not limited to, therapeutics such as a biological (e.g., Enbrel® (etanercept, TNF-receptor /Fc fusion protein, TNF blocker), anti-TNF antibodies such as adalimumab, infliximab, certolizumab pegol, and golimumab; anti-IL-12 antibodies such as ustekinumab, other Fc fusions such as CTL4A:Fc also known as ~~abacept~~abatacept; Neulasta® (pegylated ~~filgastrim~~filgrastim, pegylated G-CSF, pegylated hu-met-G-CSF), Neupogen® (filgrastim , G-CSF, hu-met- G-CSF), Nplate® (romiplostim), Vectibix® (panitumumab), Sensipar® (cinacalcet), and Xgeva® and Prolia® (each ~~denosamab~~denosumab, AMG 162); as well as other small molecule drugs, a therapeutic antibodies, a polypeptides, proteins or other chemicals, such as an iron (e.g., ferumoxytol, iron dextrans, ferric glyconate, and iron sucrose). The therapeutic may be in liquid form, or reconstituted from lyophilized form.

[0078] Among particular illustrative proteins that can be used in the syringe(s) or other primary container(s) of the AI device are antibodies, peptibodies, pegylated proteins,

CLAIMS

What is claimed is:

1. An injector for delivering a therapeutic product comprising a flexible base having a surface that conforms to various body contours of a patient, the surface defining an injection chamber therein.

2. The injector of claim 1, further comprising a cover disposed over the base.

3. The injector of claims 1 or 2, wherein the surface comprises a flexible layer for forming a vacuum between the flexible layer and the skin of the patient.

4. The injector of claim 3, wherein the flexible layer ~~that~~ stretches or pinches the skin.

5. The injector of claim 1 or 2, further comprising a flexible isolator disposed over the injection chamber, the isolator for drawing a portion of the skin up into the injection chamber defined in the surface.

6. The injector of claim 5, wherein the isolator has a concave surface for drawing the portion of the skin up into the injection chamber defined in the surface.

7. The injector of claim 1 or 2, further comprising:

a syringe disposed within the injector containing a therapeutic product;

a needle shield removably attached to the syringe; and

a peelable substrate disposed over the surface for removing the needle shield from the syringe.