

Syringe for Injectable Fillers

(2/3/06)

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Function: The goal of this project is to develop a syringe that is used in plastic surgery and delivers a known increment of injectable filler, such as autonomous fat or Sculptra®, without regard to the pressure applied to the plunger of the syringe. These fillers are injected into various tissues of varying densities and as the needle moves from a more dense tissue (dermis) to a less dense tissue (subcutaneous fat), the pressure required on the plunger is significantly decreased. One filler in particular, human fat, can clump therefore requiring a large force to dispel it. Due to this increased force or decreased density of the tissue, excess filler can be injected into the patient and lead to an uneven look under the skin. In addition to the aesthetics of this procedure, a more standard method of injecting fillers is preferred for plastic surgeons. If a consistent amount is delivered each time without regarding various human errors and ranges, the procedure is easier to perform and oversee. The incremental mechanism of this device will also allow the physician to focus on the location of the needle under the skin instead of the amount left in the syringe. There is a current device on the market similar to what we have been asked to develop. The device should be disposable or made of an autoclavable material such as metal.

Client Requirements:

- Delivers known amount of filler with one depression of plunger
- Compact design
- Syringe volume of 1cc and 5cc
- Made of metal or disposable

Design Requirements:

1. Physical and Operational Characteristics

A. *Performance Requirements* – The volume of each increment should be from 50 to 100 μL , preferably closer to 50 μL . If the product is made of plastic, it will only be a one-time use. If metal is used, it should withstand use and abuse for at least 10 years.

B. *Safety* – A standard needle will be attached so appropriate caution should be used when handling the device. There should be no sharp edges on the device. If the device is disposable; no safety legislations apply since only the needle is invasive. If the device is for continued use, sterilization measures would apply.

C. *Accuracy and Reliability* – The range of error must lie within 5-10%, and a

consistent error is preferred over imprecise values.

D. *Life in Service* - If the device is made of plastic, it will be disposable. The same device may be used multiple times for one patient during one operation. If it is made of metal, it should last up to 10 years.

E. *Shelf Life* – The shelf life of the device should be 5-10 years.

F. *Operating Environment* – The device will be stored and operated in room temp (~20°C). While in operation the environment will be sterile, also requiring syringe and/or device to be sterile. Syringe/device must withstand autoclave temperatures of 121°C.

G. *Ergonomics* – Strain on the fine hand and forearm muscles should be reduced as much as possible. Rotation of the thumb in operation should be minimal.

H. *Size* – A handheld device with no obstructions at least 5 cm from the distal end of the syringe. The device should be fit either a 1cc or 5cc syringe.

I. *Weight* – The total weight of the syringe and device should be less than 1kg, but of course the goal is to be as light as possible.

J. *Materials* – The syringe should be made of a non-porous material. Medical grade plastic, titanium, and stainless steel are possibilities.

K. *Aesthetics, Appearance, and Finish* – A window is necessary on the device in order to see the volume of filler left in the syringe. The finish should not be too shiny to reduce glare. There should be some attempt to make it attractive to patients.

2. Production Characteristics:

A. *Quantity* – Only one prototype is requested at this time.

B. *Target Product Cost* – The cost should be kept to a minimum, but a budget of \$500 is provided by the client

3. Miscellaneous:

A. *Standards and Specifications* – There are no known standards for a syringe of this type at this moment.

B. *Customer* – The client would prefer that finger rings are attached to the end of the syringe where it is held. This increases the stability of the syringe. Metal is preferred over plastic for durability. Rotation of the thumb should be minimal.

C. *Patient-related Concerns* – The syringe will need to be autoclaved between uses in patients.

D. *Competition* – Byron Medical is a company that makes the device, the Disposa-Ject™, which is very similar to what our client is requesting.