



The Criteria for Development and Acceptance of Any Safety Syringe

The following criteria are necessary for consideration by hospital administration, purchasing, technical staff and nursing staff, as well as by any manufacturer who would undertake the full development of *any* Safety Syringe product. The *Protectus Safety Syringe* is the only device that meets all of these.

1. Above all else, the Safety Syringe must be *efficacious* and prevent accidental needlestick injuries in virtually all healthcare circumstances and settings.
2. The Safety Syringe device must be a fully functional hypodermic syringe with complete all FDA permissions and approvals for use in the US.
3. The Safety Syringe device must be available in all common sizes, be able to accommodate any standard needle up to 1.5 inches in length and must be amenable to standard packaging and sterilizations technologies.
4. The Safety Syringe device must be an integral part of the syringe, not an accessory, and must be useable in a manner similar to standard syringes in all routine procedures.
5. The Safety features should be as simple as possible and the safety device should require little or no training to use effectively.
6. Safety features must activate *automatically* if the user loses or otherwise does not have intentional control of the device, i.e., the device must be *self-sheathing* to be in compliance with the US Occupational Safety & Health Administration (OSHA) mandate.
7. The Safety Syringe device must allow the user's hands to remain *behind* the needle during use, esp. during deployment of the Safety feature, so as to preclude the need for movement of the hands or fingers toward a contaminated needle; the Safety feature must provide a fixed barrier between the hands and the needle when not in use.
8. The Safety device must be user-friendly in all applications, i.e., it must be easy to manipulate while being safe and effective.
9. Users must be able to safely change the needle before injection, if necessary, to prevent vial contamination or to allow a different gauge/length needle to be attached to the syringe.
10. The Safety Syringe must have a *permanent lock* feature that disables the device and *prevents* reuse.
11. The Safety Syringe *must not* be lockable with the needle still exposed. The Safety features must continue to be in effect after disposal and should minimize additional disposal bulk.
12. Manufacture of the Safety Syringe must be *cost-effective*, thus enabling the device to be competitively marketed.