

# *Protectus Medical Devices, Inc.*

## *The Criteria for Development and Acceptance of a Safety Syringe*

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

1. The Safety Syringe device must be a functional hypodermic syringe with full FDA approval.
2. 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 use standard packaging and sterilizations technologies.
3. 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 procedures.
4. The Safety features should be as simple as possible and the safety device should require little or no training to use effectively.
5. Safety features must activate **automatically** if the user does not have, or loses, intentional control of the device, i.e., the device must be **self-sheathing** to be in compliance with the U.S. Occupational Safety and Health Administration (OSHA) mandate.
6. The Safety Syringe device must allow the worker'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 in the direction of the used needle; the safety feature must provide a fixed barrier between the hands and needle when not in use.
7. The Safety device must be user-friendly in all applications, i.e., it must be easy to manipulate while being safe and effective.
8. Healthcare practitioners must be able to safely change needles before injection, if necessary, to prevent vial contamination, or to allow a different gauge/length needle to be attached to the syringe.
9. The Safety Syringe must have a permanent locking feature that disables the device and *prevents* reuse.
10. The Safety Syringe **must not** be lockable with the needle exposed. The safety features must be in effect after disposal and should minimize additional disposal bulk.
11. Manufacture of the Safety Syringe must be **cost-effective**, thus enabling the device to be competitively marketed.