NovaGuard® SA Pro Safety System: Summary of Design Verification Testing (DVT)

I. Introduction

A. Executive Summary

This technical report summarizes the Design Verification Testing (DVT) of the NovaGuard® SA Pro 1.0 mL Long and 0.5 mL safety systems. The successful results obtained from this testing confirms the safety and efficacy of the NovaGuard® SA Pro 1.0 mL Long and 0.5 mL safety systems design in meeting their design specifications.

B. Background

The NovaGuard® SA Pro 1.0 mL Long and 0.5 mL safety systems are syringe accessories designed to accompany an ISO 11040-4 compliant 1.0 mL Long and 0.5 mL Pre-filled Syringe ❺ (PFS) respectively with a Rigid Needle Shield ❹ (RNS) (See Figure 2). Their purpose is to help prevent needle stick injury after the syringe is used. When operated by user action, the NovaGuard® SA Pro safety system elongates to cover the used needle (see Figure 1).

The NovaGuard® SA Pro 1.0 mL long safety system shown in Figure 2 is composed of two plastic injection molded components (Sleeve ❶, Syringe Holder ❸) and one metal component (Compression Spring ❷). The NovaGuard® SA Pro 0.5 mL safety system is identical but shorter in overall length. The NovaGuard® SA Pro safety system integrates a syringe clipping mechanism into the syringe holder (see Figure 2, component ❸). The result: syringe insertion becomes a single-step process, enabling existing syringe assembly lines to easily accommodate the NovaGuard® SA Pro safety system with minimal adjustment and change parts.

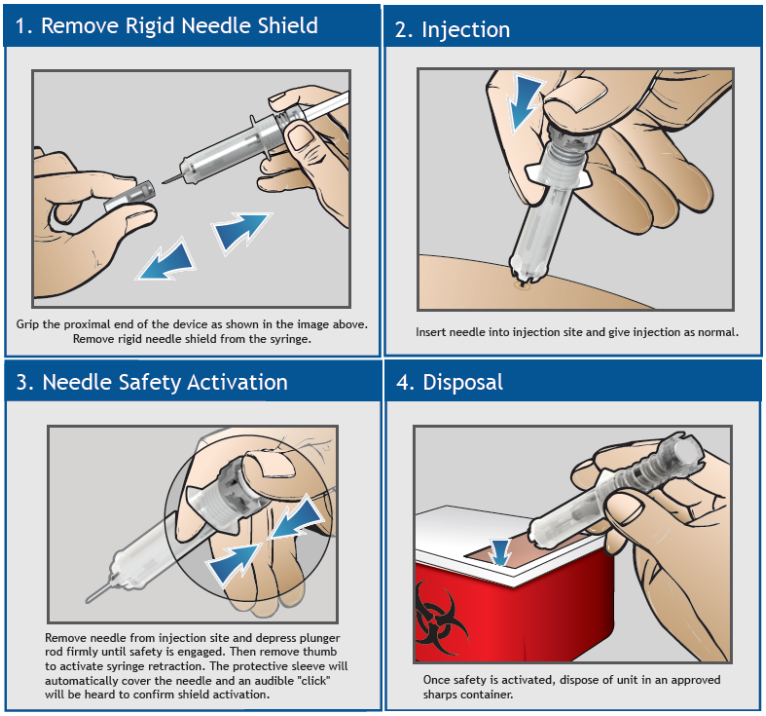

Figure 1: How it works

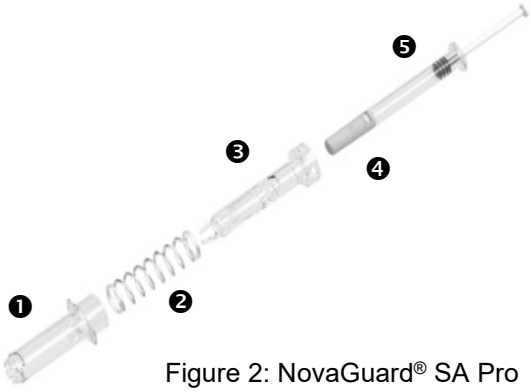

Figure 2: NovaGuard® SA Pro 1 mL Long Safety System with Pre-Filled Syringe

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II. Experimental Details of Design Verification Testing (DVT)

1. NovaGuard® SA Pro safety system test samples were subject to climate conditioning (as per ASTM D4332-14); and transport simulation testing (as per ASTM D4169-16, ASTM D5276-98, ASTM D999-08 and ASTM D4728-06) at an independent test facility prior to DVT functional testing.

2. One batch was used for T0 (unaged) testing, with the remaining batches placed into temperature and humidity-controlled environments for aging. Batches were stored at accelerated aging conditions and tested at specified time intervals to simulate up to 5 years real-time equivalent; the remaining batches are being stored at room temperature conditions and will be tested each year, real-time, up to five years.

3. The below list describes key tests performed during Design Verification Testing.
   - Transport Simulation
   - Syringe assembly force
   - Activation security and sound
   - Pre-activation disassembly force
   - Drop test, pre- and post-activation
   - Activation and safety lock
   - Tensile disassembly, pre- and post-activation
   - Safety force, post-activation
   - Needle retraction depth, post-activation
   - RNS removal and replacement

III. Summary

Unaged batches (T0) for NovaGuard® SA Pro 1.0 mL Long and NovaGuard® SA Pro 0.5 mL safety systems passed each test by meeting the pre-determined acceptance criteria.

Accelerated aged batches (up to 5 years real-time equivalent) for NovaGuard® SA Pro 1.0 mL Long and NovaGuard® SA Pro 0.5 mL safety systems passed each test by meeting the pre-determined acceptance criteria.

The results obtained from design verification testing of unaged and accelerated aged NovaGuard® SA Pro safety system confirms the adequacy of the NovaGuard® SA Pro safety system in meeting the design input specifications and a shelf life of 5 years.

Multi-year real-time aging and testing of NovaGuard® SA Pro 1.0 mL Long and NovaGuard® SA Pro 0.5 mL safety systems up to 5 years is on-going.

IV. Acronyms

Acronym	Explanation
ASTM	American Society for Testing and Materials
DVT	Design Verification Testing
ISO	International Standards Organisation
PFS	Pre-Filled Syringe
RNS	Rigid Needle Shield

V. Reference Documents

Document Number	Title
ISO 11040-4/A1: 2020	Pre-Filled Syringes – Part 4: Glass barrels for injectables
EN ISO 23908: 2013	Sharps Injury Protection – Requirements and Test Methods
EN ISO 11608-1: 2015	Needle-based Injection systems for medical use
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332-14	Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D999-08 (2015)	Test Methods for Vibration Testing of Shipping Containers
ASTM D4728-06 (2012)	Test Method for Random Vibration Testing of Shipping Containers
ASTM D5276-98 (2009)	Test Method for Drop Test of Loaded Containers by Free Fall

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This technical report dated 28 March 2022 is the second release version of this report and supersedes the previous version.