NovaGuard™ SA Pro Safety System: Confirmation of Safety and Efficacy through Design Verification Testing (DVT) – A Brief Summary

I. Introduction

A. Executive Summary

This technical report summarizes the Design Verification Testing (DVT) of the NovaGuard™ SA Pro Safety System. The successful results obtained from this testing confirms the safety and efficacy of the NovaGuard™ SA Pro Safety System design in meeting the design specification.

B. Background

The NovaGuard™ SA 1 mL Long Safety System is a syringe accessory designed to accompany an ISO 11040-4 compliant Pre-Filled Syringe ❺ (PFS) with a Rigid Needle Shield ❹ (RNS) (See Figure 2). Its purpose is to help prevent needle stick injury after the syringe is used. When operated by user action, the NovaGuard™ SA Pro elongates to cover the used needle (see Figure 1).

The current NovaGuard™ SA 1 mL Long Safety System, shown in Figure 2, is composed of three plastic injection molded components (Sleeve ❶, Syringe Holder ❸, and Clip ❻) and one metal component (Compression Spring ❷). In contrast, the NovaGuard™ SA Pro Safety System integrates a syringe clipping mechanism into the syringe holder (see Figure 3, component ❸), thereby containing fewer components and eliminating the need for an additional assembly machine. The result: syringe insertion becomes a single step process, enabling existing syringe assembly lines to easily accommodate the NovaGuard™ SA Pro with minimal adjustment and change parts.

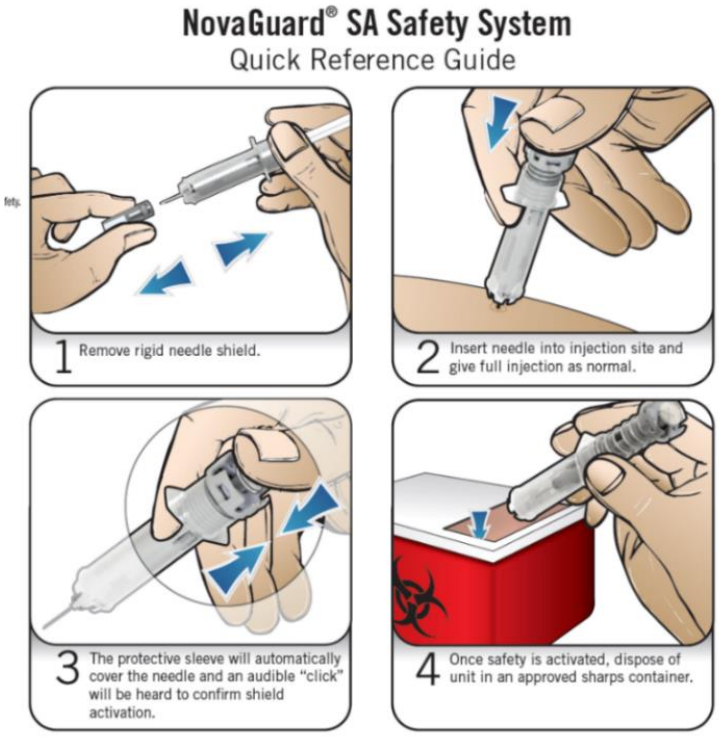

Figure 1: How it works

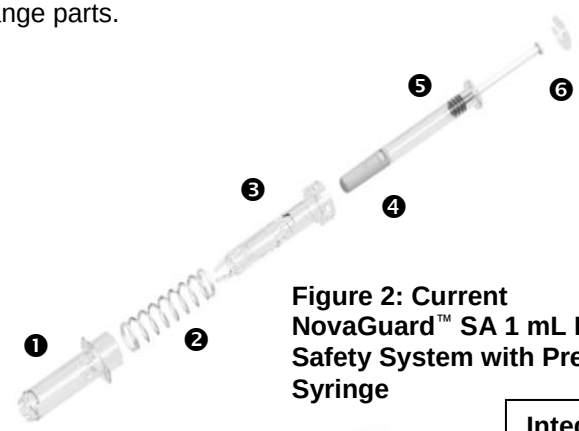

Figure 2: Current NovaGuard™ SA 1 mL Long Safety System with Pre-Filled Syringe

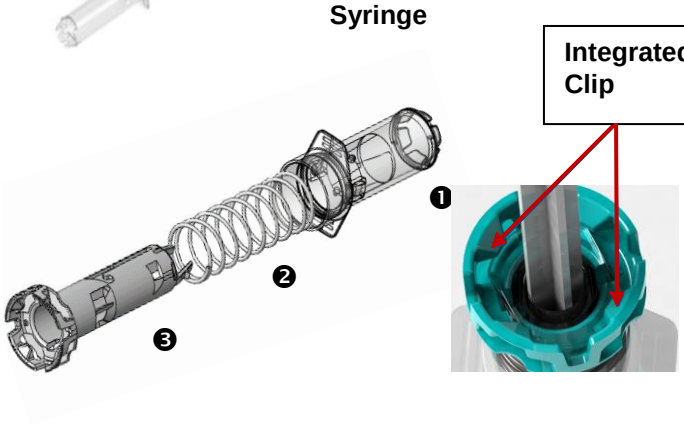

Figure 3: NovaGuard™ SA Pro Safety System - Integrated Clip Design (PFS not shown)

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II. Experimental Details of Design Verification Testing

1. A total of 8,800 samples were put through 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 functional testing.

2. Samples were subsequently inspected, divided into 11 batches and labeled. One batch was used for T0 testing, with the remaining ten being placed into temperature and humidity controlled environments for aging. Five were stored at accelerated aging conditions and tested at times to simulate up to 5 years real-time (according to the Arrhenius equation); the remaining five are being stored at room temperature conditions with plans to be tested at each year, real-time, for up to five years.

3. At each accelerated aging time point, 800 samples were visually inspected and then divided into 10 sets. The number of samples in each set, and subsequently each test, was determined based on a product design risk assessment and the criticality of each test, i.e. whether a test assesses the primary operating features of the NovaGuard™ SA Pro Safety system for sharps injury prevention. Multiple tests were run on each sample set, culminating in a destructive test.

4. The below list describes the tests which comprised the Design Verification Testing.

- Transport Simulation
- Syringe assembly force
- Ability of syringe to be rotated
- Activation security and sound
- Pre-activation disassembly force (force applied to RNS or cannula)
- Drop test, pre- and post-activation
- RNS removal force and replacement
- Activation and safety lock
- Tensile disassembly, pre- and post-activation
- Safety force, post-activation
- Needle retraction depth, post-activation
- Bend test, post-activation
- Clip impact test

III. Results Summary

The unaged (T0) batch passed every test by meeting each pre-determined acceptance criteria. Test data for batches that completed accelerated aging to the equivalent of 1, 2, 3, 4, and 5 years real-time also met pre-determined acceptance criteria. Real-time aging and testing is on-going.

IV. Discussion and Conclusions

A. The NovaGuard™ SA Pro samples tested were manufactured, inspected and released by West using processes previously qualified and currently being used in the manufacture of saleable NovaGuard™ SA product.

B. Representative samples of the NovaGuard™ SA Pro were subjected to functional testing in accordance with an in-house design input specification (DIS).

C. Test acceptance criteria was met for all tests. The successful results obtained from design verification testing of unaged and accelerated aged NovaGuard™ SA Pro product confirms the adequacy of the NovaGuard™ SA Pro in meeting the design input specification.

V. Acronyms

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

VI. Reference Documents

Document Number	Title
ISO 11040-4	Pre-Filled Syringes – Part 4: Glass barrels for injectables
ISO 23908:2011	Sharps Injury Protection
ISO 11608-1:2014	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

West's products are sold on the basis that it is the customer's responsibility to evaluate and test the West product to determine its compatibility with other materials and fitness for any end use.

This technical report, dated 11 July 2017, is the first release version of this report.