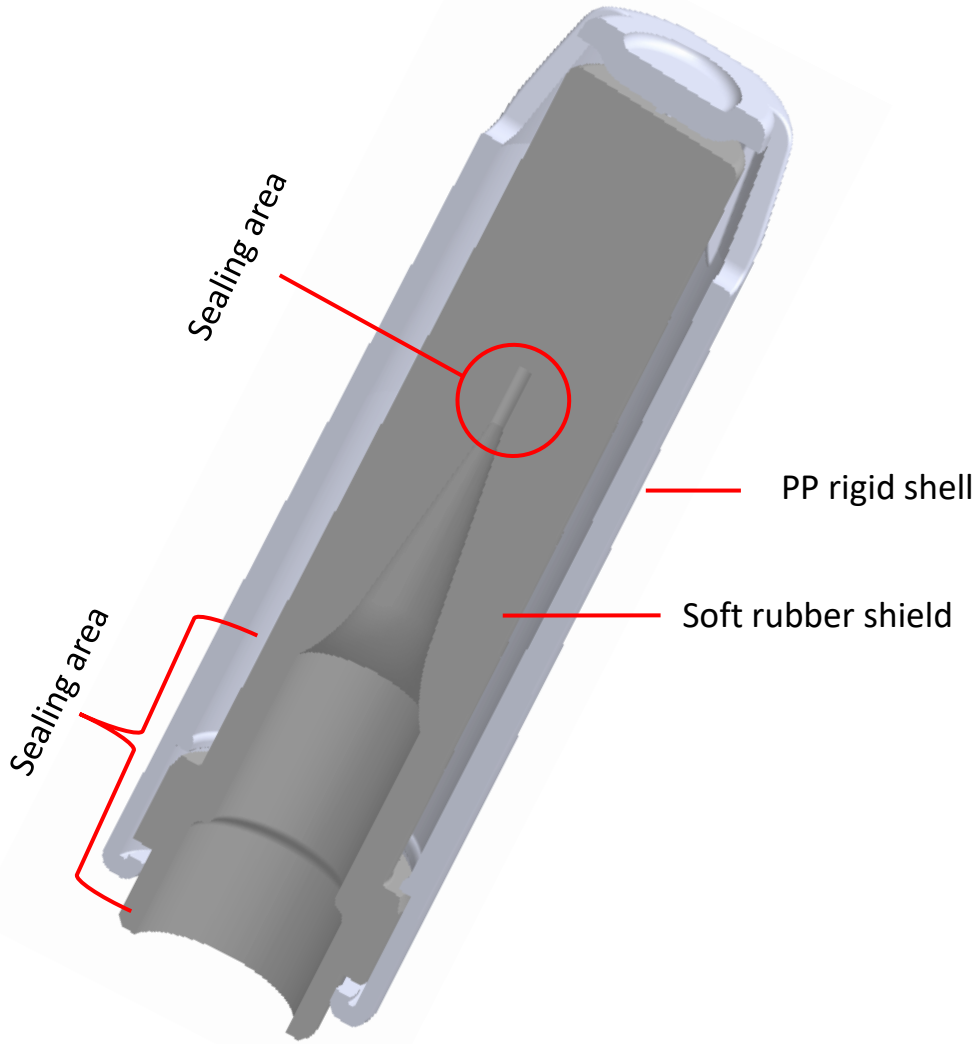
West Rigid Needle Shields for Staked-Needle, Pre-Filled Syringes

We've Got It Covered!

West Pre-Filled Syringe Components

- Syringe plungers/pistons
- Rigid and soft needle shields
- Tip caps
- Plunger rods

West Rigid Needle Shields: Protection & Safety



- Needle shields with rigid covers are recommended closures for prefilled syringes protecting the hypodermic needle tips through de-shielding via an optimized design.
- Combines the sealing properties of soft rubber shields with the rigidity of a polypropylene (PP) shell safeguarding against needle tip damage and deformation
- Manufactured from elastomers especially designed for prefilled syringe applications
- Helps assure container closure integrity through two sealing areas
- Designed to dimensionally fit ISO 11040-4 glass syringes with staked needles

* *7025/65 is not steam sterilizable in assembled syringe format*

Formulation

- Formulation 7028/55[1] designed for needle shields
- High resistance to ozone cracking[2] helping ensure container closure integrity

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- Designed for compliance with applicable EP and USP compendia
- Reduced risk of coring and fragmentation[3]
- Less susceptible to frosting, visual discoloration and blooming than traditional elastomers

In-Process Excellence

- Tight dimensional tolerances achieved through precision injection molding providing confidence
- In-process automated camera inspection resulting in dimensional reliability for processing

- Dimensional specifications with tight tolerances
- Designed for easy distribution and orientation on syringe assembly equipment from different vendors
- Utilizes existing assembly machine and filling equipment with minor adjustments
- Suitable for polymer (e.g., COP) syringes
- Usable with needles with safety features

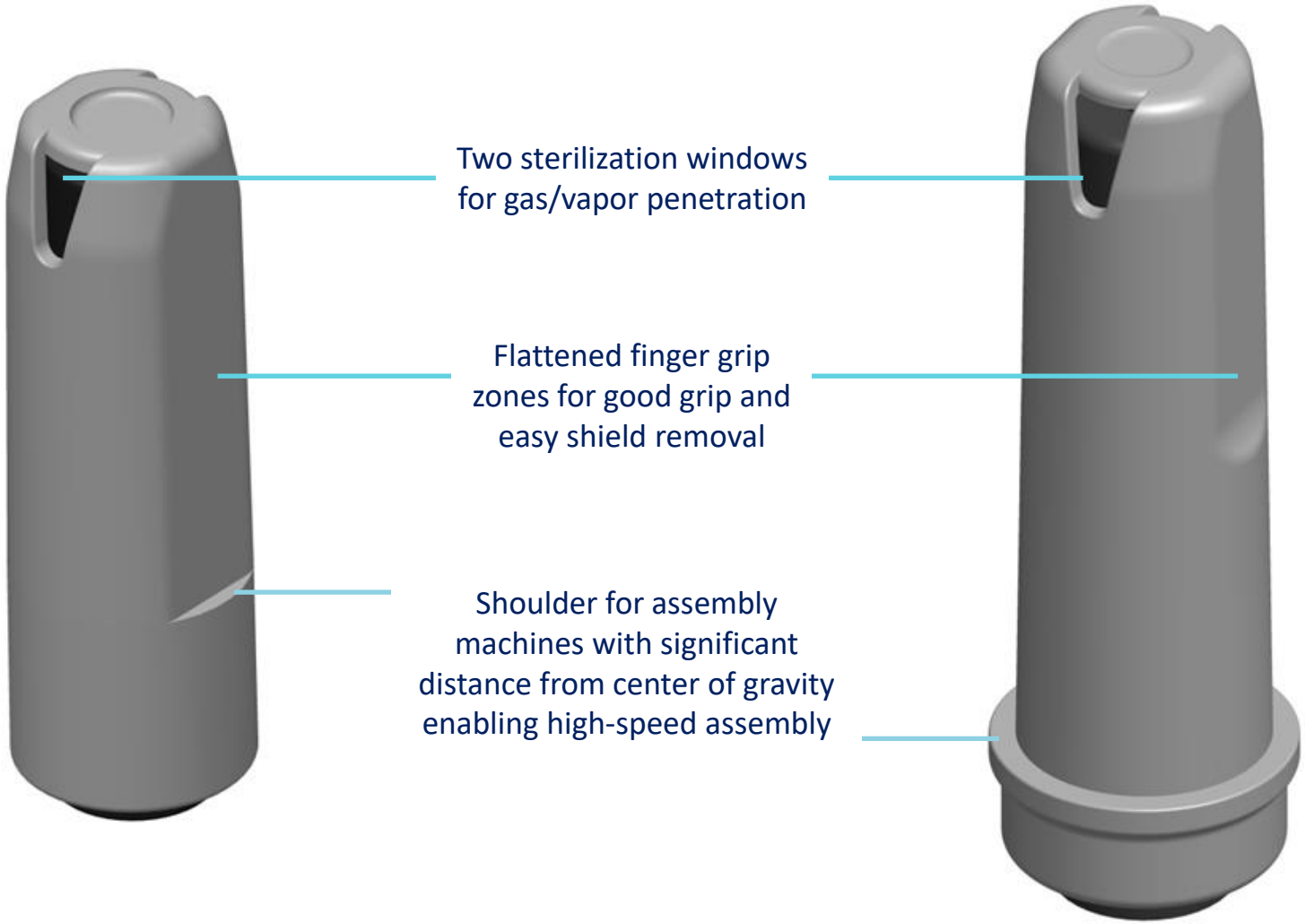
Extensively Studied with Industry Partners

- Extensively studied in collaboration with industry partners to characterize[3] reaffirming performance

- Reduced risk of pop-off during sterilization or pressurization[3]
- Ability to remain intact under high separation force[3]
- Pull-off force enabling controlled and seamless shield removal[3]

1. Formulation Characteristics, Elemental Extractables and Nitrosamines Data Sheets supported by Compliance Bulletins available upon customer request
2. Technical Document: The Effects of Ozone and Various Sterilization Techniques on Elastomeric Rubber Needle Shields and Tip Caps
3. TR 2018/183 West 5/8“ RNS Product Characterization and TR 2018/182 West 1/2“ RNS Product Characterization

Available in Two Sizes & Two Rubber Formulations*



RNS™ 1/2” (13mm) – Design 4144 | **RNS™ 5/8” (16mm) – Design 4145**

*7028/55 and 7025/65 rubber formulations

7028/55 Rubber Formulation Details

Parameters	7028/55 Rubber Formulation[1]
Base Polymer	Synthetic Polyisoprene - Proprietary Elastomer Blend
Dry Natural Latex Rubber	Not Used As Raw Material
EP 3.2.9 chem. tests, USP <381> physicochem. tests	Complies to Type I
CHP & YBB Compliance	Current China National Standards[2]
Coring	Low[3]
Gas & Vapor Permeability	High[3]
Frosting & Blooming	Low[4]
Sterilization Compatibility	Steam, EtO and Gamma Irradiation[5, 6]
Resistance to Ozone Cracking	High[6]
Extractables & Leachables (E&L)	Low[4]
Extractable Elements	Zinc[7]

1. Formulation Characteristics, Elemental Extractables and Nitrosamines Data Sheets supported by Compliance Bulletins available upon customer request
2. Not applicable for all part codes; request for China letter of authorization process
3. TR 2018/183 West 5/8‘‘ RNS Product Characterization & TR 2018/182 West 1/2‘‘ RNS Product Characterization
4. Data on file at West
5. Steam sterilization is not recommended for assembled prefilled syringes with a staked needle due to the adhesive used to assemble staked needles; rigid cover has potential of color change after gamma irradiation
6. Technical Document: The Effects of Ozone and Various Sterilization Techniques on Elastomeric Rubber Needle Shields and Tip Caps
7. Alternative rubber formulation 7025/65 offered with lower zinc levels; reference the Elemental Extractables Data Sheet for 7028/55 and 7025/65

Difference Is In West Manufacturing Process

The difference is in the West manufacturing process

- West has a process to manufacture (soft) needle shields using a Precision Injection Molding (PIM) Cell approach
  - Approach is a combination of PIM and primary vision inspection
  - PIM molding technology yields components with tight tolerances and precise geometry
  - Automated visual inspection offers industry leading quality

- Siliconization is tailored for the rubber formulation and design
  - Constant wash load process obtains a consistent silicone oil application within a target output range

- Frequent manufacturing in-process-quality controls (IPC) ensure exact components
  - IPC release criteria incl. dimensions, siliconization level, particulate, bioburden, and endotoxin

West Rigid Needle Shield Specifications

West RNS™
Rigid Needle Shields

- Visual
  - According to AQL calculation
- Pull Off Force
  - Pull-Off-Forces 5N ≤ X ≥ 35N
- Standard Dimensions
- Endotoxin level:
  - ≤ 0.25 EU/cm²
- Bioburden level:
  - ≤ 2.5 CFU/10 cm²
- Particle Counting Index [PCI]
  - ≤ 6 / 10 cm²

RNS™ Rigid Needle Shields Performance Evaluation

- Extensive study in cooperation with industry professionals
- Test Program: Functional testing over time; Machinability; Transport Simulation

Functional testing on all design-rubber combinations:

Pull-off Force [N]

- Important for proper de-shielding of the RNS from the syringe by patients or caregivers.
- Pull-off-Force: 5-35 N

Separation Force [N]

- The rigid shell must be well joined with the flexible rubber component to guarantee a safe handling when disengaging the RNS from the syringe
- Removal force ≥ 50 N

Coring

- During RNS assembly on the syringe the needle may punch out fragments from the rubber component. Fragments represents a critical risk for the injection.

Pop-Off/Movement

- Simulation of steam sterilization and air transport which bares the risk of RNS movement on the syringe or pop off leading to the loss of integrity.
- RNS Movement ≤ 0,5 mm

Leak Test

- To ensure integrity of assembled RNS syringes are filled with WfI and an increasing pressure is applied to the plunger and the leakage is tracked.

Ethylene Oxide Sterilization

- Verify the EtO sterilizability of RNS assembled syringes with bioindicator spore strips. The rubber formulation and the windows of the rigid shell allow an appropriate gas/vapor penetration

EtO Residual

- Levels of remaining EtO and ethylene chlorodyne were tested compliant with ISO 10993-7

Source Data: TR 2018/183 West 5/8‘‘ RNS Product Characterization & TR 2018/182 West 1/2‘‘ RNS Product Characterization

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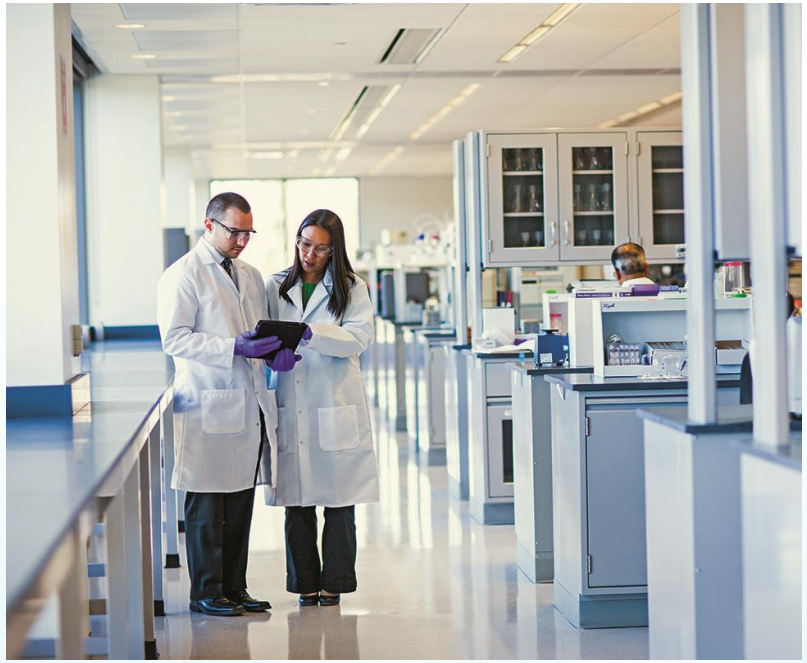
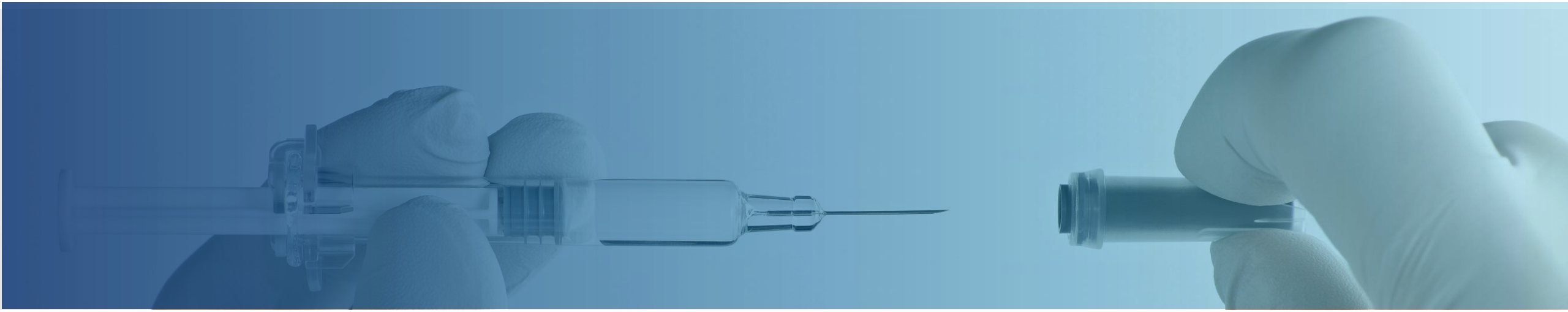
West

West RNS™
Rigid Needle Shields



Thank You!



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