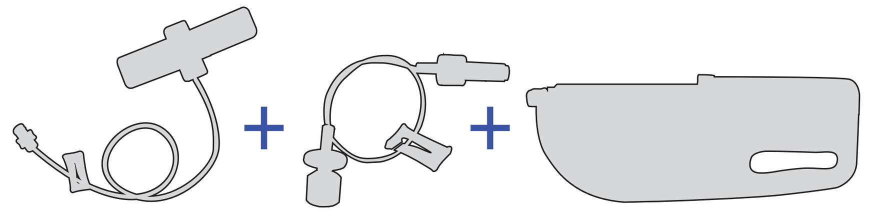
Subcutaneous Needle Sets (SNS) Impact Patients Undergoing Subcutaneous Immunoglobulin (SCIg) Treatments

Background

Optimal SCIg treatment depends on selection of SNS and the entire infusion technology used. Electric constant flow systems (CFS) will increase pressure as needed to maintain the flow rate which can create a risk of high pressure forcing immunoglobulin into the dermal layers producing an infusion-site reaction. Constant pressure systems (CPS) operate at safer and considerably lower pressure which for an optimal performance requires low resistance SNS with consistent flow output to deliver high viscosity products at high flow rates.

For optimal infusion performance:



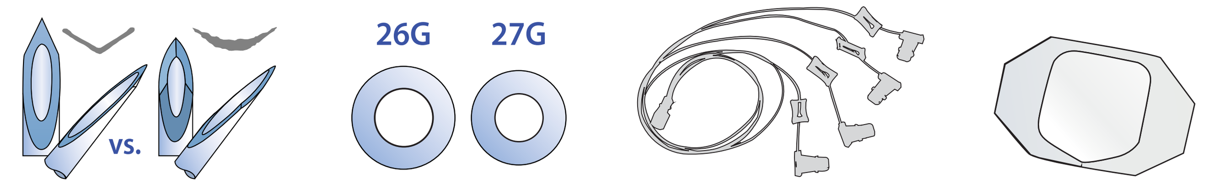
Viscous drug delivery at high flow rates

low resistance high flow 26G SNS | flow rate tubing | Constant Pressure System (CPS)

Purpose

Determine important parameters for selection of SNS with CPS for SCIg infusions. Investigate needle tip design, gauge, flow resistance and evenness of flow in multi-site sets, and type of dressing to optimize infusion results.

Important parameters:



needle tip design | needle gauge | flow in multi-site sets | site dressing

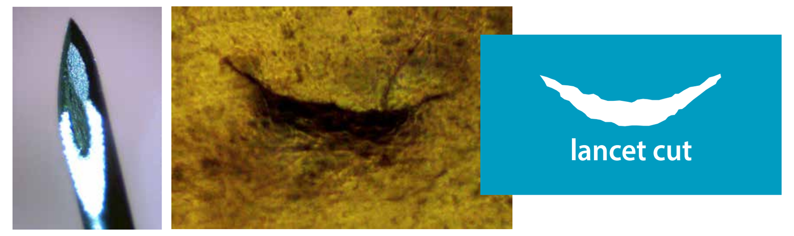
Contributing authors:

Fred L. Ma, M.D.,Ph.D.[1], Chatarina Soderman, RN. MBA[2], Andrew Sealfon[3], Paul Mark Baker M.D[4]

[1] Chief Medical Officer, RMS Medical Products, [2] VP of Product Marketing & Clinical Affairs Associate, RMS Medical Products, [3] President, RMS Medical Products, [4] Crystal Run Healthcare

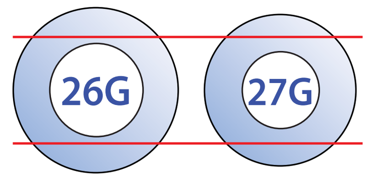
Tricuspid vs. Lancet tip:

Tricuspid with actual penetration in simulated skin, low damage entry.



Lancet needle actual penetration in simulated skin, more coring and tissue trauma.

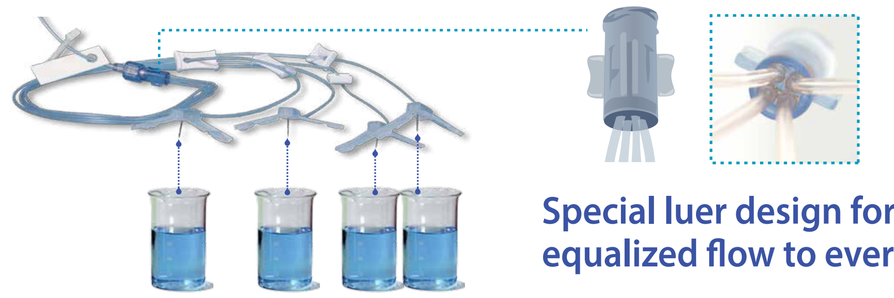
Needle gauge:



The gauge number only speaks to the outside diameter, but it is actually the inner diameter that effects the flow resistance.

The laminar flow rate capacity of the high flow 26G needle is 335% greater compared to the 27G.

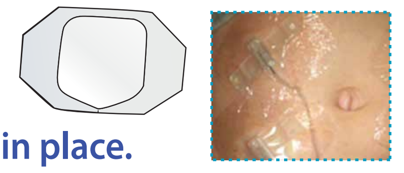
Even flow in multi-sets:



Special luer design for dependable, equalized flow to every needle.

Needle site dressing:

Clear, non-irritating, infusion-site dressing allows for easy monitoring while securing needle in place.



Methods

Literature review on needle configuration and pain was performed. Available on the market SNS were compared. Flow measurements were made with bench testing comparing flow and pressure performance in a variety of different gauges and configurations. Patient studies were undertaken with groups of 30 and 58 patients using high flow 26 gauge SNS.

Results

The CPS with a 26 gauge, low resistance SNS, can administrate 20% immunoglobulin at a flow rate exceeding 37ml/hr at a very low 13.5 psi (0.93 bar) pressure. Literature findings on subcutaneous injection pain shows it is associated with bluntness of the needle tip but is not related to the needle diameter in the range of 26 – 28 gauge sizes. 29 out of the 30 patients who previously had used a different SNS reported less pain on insertion with the 26 gauge tricuspid needle tip. They also reported improved flow rate with shorter administration times when no other parameters were changed. Evaluation from 58 patients using the same SNS demonstrated that 94% find it very easy to grip the wings and place the needle, 85% use the transparent dressing supplied and 99% find it easy to activate the needle protection after use.

CPS with use of 26G high flow SNS:

- Administers Ig at high flow rates
- Special luer design for equalized flow to multiple infusion-sites
- Maintains constant low, safe pressure, allowing for immediate response if tissue saturation occurs.
- Continuous improvement cycle can be created

30 Patient Survey

- 29 of 30 patients reported less pain on insertion with tricuspid needle
- Improved flow rate
- Shorter infusion times
- Improved infusion site outcomes

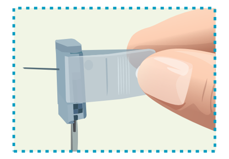
tricuspid needle tip

less time

Optimal infusion site outcome directly after infusion

58 Patient Survey

- 94% found it easy to grip and insert needles
- 85% use the transparent dressing supplied
- 99% found safety closure feature easy to use
- 95% satisfaction rate with the 26 gauge SNS



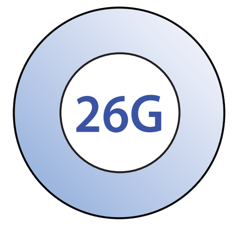
easy-grip wings

safety closure

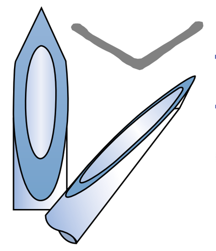
Conclusion

The optimum SNS in a CPS is the 26 gauge SNS which deliver high flow rates at the lowest pressures. It also provides improved tolerability, consistency and even flow to each needle in a multi-set. The tricuspid tip design seems to minimize tissue damage and pain. The wing design allows easy placement of the needle and easy activation of the needle-protective cover. The transparent cover dressing secures the SNS in place and allows for easy removal after completion of infusion. Satisfaction rate of the 26 gauge SNS was 95%.

26G high flow is the SNS of choice

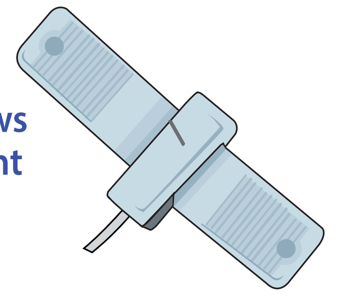


Optimum gauge for delivery of high flow rates at lowest pressures.

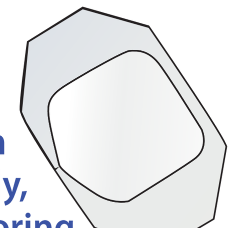


Tricuspid tip design for minimal tissue damage and pain.

Wing design allows for easy placement and activation of safety feature.



Clear dressing secures needle in place comfortably, allows for monitoring and is easy to remove.



References:

1. Immunoglobulin National Society, IgNS Nursing Standard of Practice, First edition 2015.
2. S. Jolles, J.S Orange, A. Gardulf, M.R. Stein, R. Shapiro, M.Borte and M.Berger, 2014, Current Treatment Options with Igg for the Individualization of Care in Patients with PID, British Society for Immunology, Clinical and Experimental Immunology 179: 146-160.
3. Ochoa D, Curtis C, Duff C, Riley P, Murphy E and Zampelli A. 2012. Importance of Ancillary Supplies for Subcutaneous Immunoglobulin Infusions: Management of the Local Infusions Site, Journal of Clinical Immunology 32 (Supplement 1): 347.
4. Sealfon A and P.M Baker. 2012. Impact of Needle Sets on Patient Infusion Sites Reactions from Delivery of Subcutaneous IgG (SCIg), Journal of Clinical Immunology 32 (Supplement 1): 405.
5. E Chantelau, D.M Lee, D.M Hemmann, U Zipfel and S Echterhoff, 1991, What Makes Insulin Injections Painful?, BMJ volumne 303: 26.
6. JT Jorgensen, J Romsing, M Rasmussen, J Moller-Sonnergaard, L Yang, and L Musaeus "Pain Assessment of Subcutaneous Injections", The Annals of Pharmacotherapy: Vol. 30, No.7, pp. 729-732.
7. Allison M. Okamura, Christina Simone, and Mark D. O'Leary. "Force Modeling for Needle Insertion Into Soft Tissue"; IEEE Transactions on Biomedical Engineering, Vol. 51, No. 10, October 2004.
8. S.P. DiMaio and S.E. Salcudean, "Needle insertion modeling and simulation", in Proc. IEEE Int. Conf. Robotics Automat., 2002, pp 2098-2105.
9. Mohsen Mahvash,, and Pierre E. Dupont; Mechanics of Dynamic Needle Insertion into a Biological Material; IEEE Transactions on Biomedical Engineering, Vol. 57, No. 4, April 2010.
10. Ray Lathrop, Randy Smith, and Robert J. Webster III Medical and Electromechanical Design Lab, Vanderbilt University; Needle-Membrane Puncture Mechanics (poster) http://research.vuse.vanderbilt.edu/MEDLab/index.htm.
11. Hiroyuki Kataoka, Toshikatsu Washio, Kiyoyuki Chinzei, Kazuyuki Mizuhara, Christina Simone, and Allison M. Okamura; "Measurement of the Tip and Friction Force Acting on a Needle During Penetration" Proceeding of the Fifth International Conference on Medical Image Computing and Computer Assisted Intervention—MICCAI 2002, Lecture Notes in Computer Science (Vol. 2488), T. Dohi and R Kikinis, Eds., 2002, pp 216-223.

TRS_PO4_NeedleSetImpact_IgNS2016_vA

RMS™ MEDICAL PRODUCTS

24 Carpenter Road • Chester, NY 10918 • USA