

Infusion Sets 2015: Your Critical Link to Success on a Pump

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Outline

- Today's infusion set options
- Do infusion sets, occlusions, or duration of infusion set use affect glucose?
- How do insulin infusion sets (IIS) fail?
 - Design, physiology, or technique?
 - Mechanisms: occlusions, leaks, bleeds, and site issues
 - Inspect, inquire, and diagnose
- Silent occlusions as a new source of problems
- Potential solutions

Infusion Sets in 2015: An Evolving State of the Art

- Today's sets offer many improvements and options
- Yet reports and blogs suggest IIS issues are widespread
- Surveys are helpful but only a handful of direct studies
- IIS leaks and failures create random unexplained hyperglycemia – source is difficult to identify
 - Make up most phone calls to manufacturers
 - A common reason for pump discontinuation
- Problems far more likely to come from IIS than pump
- More oversight and research of IIS is advised¹

¹ Heinemann L, Fleming GA, Petrie JR, Holl RW, Bergenstal RM, Peters AL. *Diabetes Care*. 2015;38:716-722.

Major Sign of An Infusion Set Problem: UHG

Major Sign of An Infusion Set Problem: Unexplained HyperGlycemia

Brand Loyalty

- Initial IIS often selected by pump manufacturer
- Pump wearer often does not change infusion set brand despite repeated episodes of UHG
 - Years of use of same brand: 5.2 ± 4.3 years in 1,142 pump wearers (diabetes duration 7.9 ± 6.1 years)¹

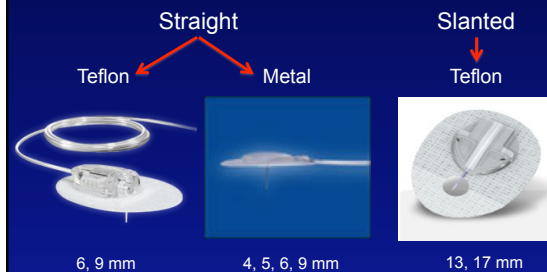
¹ Heinemann L, Weber D, Kalltheuner M, Scheper N, Faber-Heinemann G, Reichert D. Abstract #994-P. American Diabetes Association 73rd Scientific Sessions, Chicago, IL, 2013.

Solve the Infusion Set Problem

- More than one infusion set problem a month?
 - Modify your set technique
 - Change infusion set brand

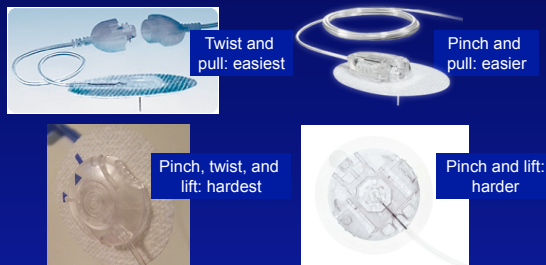
Goal: Less than 1 failure a year!

Infusion Set Options



Tubing lengths: 24, 32, and 43 inches for most sets

Disconnect Options with Manual Dexterity Requirements



Auto-Inserter Options



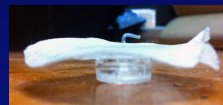
Auto-Inserters

Pro:

- Consistent insertion
- Higher perceived comfort

Con:

- Initial failure rates of 3.2%,¹ 8.9%,¹ 10%,² and 15%³
- Among 1,142 German pump wearers, 72% using an auto-inserter reported that it failed to work ~10% of the time⁴
- Failures average 0.3-2.2 times/month for 2-3 day set use



¹ Renard E, Guerci B, Leguerrier AM, Boizel R. *Diabetes Technol Ther*. 2010;12:769-773.

² Reichert D, Weber D, Kaltheuner M, et al. *Diabetes, Stoffw. und Herz*. 2013;22:367-375.

³ Patel PJ, Benasi K, Ferrari G, et al. *Diabetes Technol Ther*. 2014;16:15-19.

⁴ Heinemann L, Weber D, Kaltheuner M, Scheper N, Faber-Heinemann G, Reichert D. Abstract #994-P. American Diabetes Association 73rd Scientific Sessions, Chicago, IL, 2013.

Needle/Cannula Length

- With 90° insertion, use 4-6 mm needles.¹
- Slanted lengths of 13 mm work best for most pump users
 - Excess cannula length can kink or cause discomfort
- Longer cannulas may work better with high BMI or large bolus doses

¹ Gibney MA, Arce CH, Byron KJ, Hirsch LJ. *Curr Med Res Opin*. 2010; 26:1519-1530.

Straight or Slanted Cannula

Straight:

- Less dexterity required
- More site options
- Anchor line with tape to stop "pump bumps" and leakage

Slanted:

- More placement options in lean or muscular individuals
- Infusion site can be viewed for earlier detection of irritation, leak, or infection
- Less tunneling and leakage with longer cannulas, especially when anchored with tape

Infusion Set Use Differs in the United States and Germany

Infusion Set	United States		Germany	
	<i>n</i>	%	<i>n</i>	%
Rapid-D	4	1	103	25
Contact™ D/Sure-T	32	6	81	20
Ultraflex/FlexLink	14	3	84	20
inset™/mio®	106	21	22	5
Comfort®/Silhouette®	125	25	15	4
Quickset®	149	30	59	14
OmniPod®	37	7	20	5

Walsh J, Roberts R, Weber D, Faber-Heinemann G, Heinemann L. *J Diabetes Sci Technol*. 2015, Vol. 9(5) 1103–1110.

Steel or Teflon

Steel:

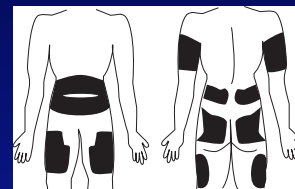
- No kinking
- Fewer silent occlusions¹
- Manual insertion
- Less failure
- Better biocompatibility and less back pressure²
- Easier to train
- 28-30 gauge

Teflon:

- More selections
- Straight or slanted
- Manual or automatic insertion
- Less needle phobia
- 25 gauge (27-gauge introducer needle)
- FlowSmart: 28 gauge (30-gauge introducer)

¹McVey E, Keith S, Herr J, Sutter D, Pettis R. *J Diabetes Sci Technol*. 2015. In press.
²Højbjørre L, Skov-Jensen C, Kastrup P, Pedersen PE, Stallknecht B. *Diabetes Technol Ther*. 2009;11:301-306.

Legs and Arms?



Muscle areas move a lot, are slower to absorb insulin except during exercise (variable insulin action), and can irritate skin from cannula motion.

Match an Infusion Set

To the individual:

- Young children
- Pregnancy
- Visual impairment
- Dexterity issues
- Low or high BMI
- Small or large doses
- Prefer auto-inserter
- Steel needle phobia

To their skin:

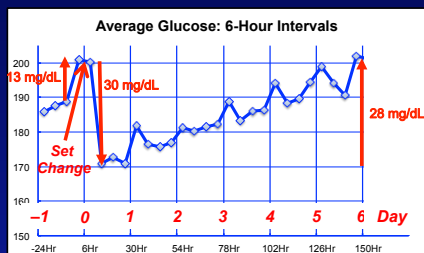
- Allergies
- Hairy torso
- Lipohypertrophy (LH)
- Scarring

And to activity:

- Sweating and swimming
- Golf, tennis, contact

Infusion Set Failure Design, Technique, or Physiology?

Glucose Levels Before and After Infusion Set Changes

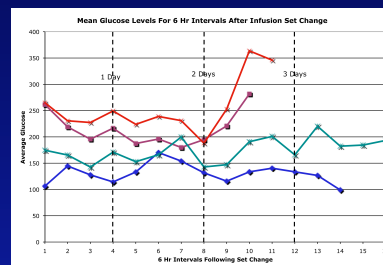


Average glucose levels for 6-hour intervals before and after infusion set change in 396 pumps (>20 set changes/pump).

Walsh J, Roberts R, Bailey T. Unpublished data from the Actual Pump Practices study.

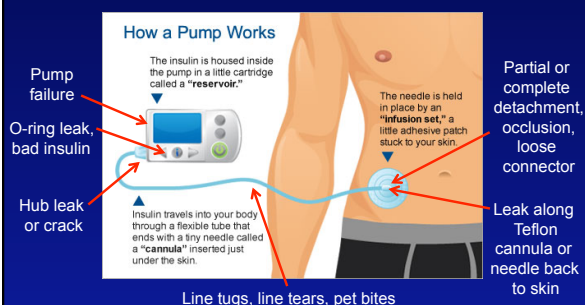
Individual Responses Vary with Length of Infusion Set Use

Avg BG of 4 individuals with over 20 set changes for each



Design, technique, or physiology?

The Weak Spots in Insulin Delivery

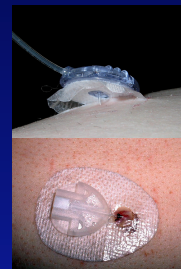


Graphic courtesy of Liberty Medical

How Infusion Sets Fail

- Failure on insertion
 - Auto-inserter failure → kink or partial detachment
- Detachment — full or partial*
- Occlusion/blockage — full or partial
- Insulin leak along cannula to skin,* at connection, or from line damage
- Bleeding at the tip of the cannula

* Often due to lack of anchoring



Goal: Less than 1 failure a year!

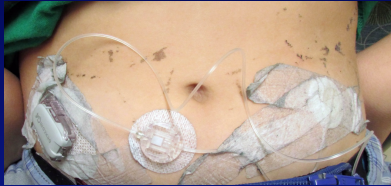
Infusion Set Questions to Ask

- How many days can you usually wear an IIS?
- Do your glucoses go up on day 2, 3, or ?
- Do sites sometimes not work?
- Do you have scarring or poor absorption?
- How often do you have UHG?
- Do correction boluses sometimes not work?
- Do some highs only correct when you change your infusion set?

If You Answer Yes, Ask Your Clinician to Help You

- **Check** meter and CGM data for UHGs
- **Inspect** your site, skin, and line anchoring
- **Review** site preparation and set insertion technique
- **Demonstrate** proper infusion set technique

Inspect the Site



Better solutions for those who swim or sweat:

- Skin Tac
- Benzoin
- Mastisol & Detachol
- Toupee glue
- Opsite Flexifix
- Hypafix
- IV3000 or Tegaderm
- Aeroskin wet suit T-shirt for long-distance swimmers

Inspect for Site Issues

Look and Feel:

- Allergies:
 - Adhesive
 - Cannula lubricant
 - Nickel in steel needle^{1,2}
- Infection/abscess
- Motion of cannula ("pump bumps" and leaks)
- LH (fat buildup from repeated use of same site)
- Scarring



¹ Mehta V, Vasanth V, Balachandran C. *Indian J Dermatol*. 2011;56:237-238.

² Raison-Peyron N, Guillard O, Khalil Z, Guilhou JJ, Guillot B. *Contact Dermatitis*. 2005;53:222-225.

Look for Lipohypertrophy

- LH is frequent: 26.1% and higher¹
- 27% insert at the same site²
- A CGM study of pump infusion into LH and non-LH areas in eight individuals found no difference in glycemic control³
- No difference in A1C (9.6 vs. 9.5%) was found between those with (32) and those without (41) LH⁴
- BG variability and hyperglycemia due to delayed absorption in LH is more likely when subcutaneous scarring is present^{4,5}



¹ Pickup JC, Yemane N, Brackenridge A, Pender S. *Diabetes Technol Ther*. 2014;16:145-149.

² Heinemann L, Weber D, Kaltheuner M, Scheper N, Faber-Heinemann G, Reichert D. Abstract #994-P. American Diabetes Association 73rd Scientific Sessions, Chicago, IL, 2013.

³ Overland J, Molyneaux L, Tewari S, et al. *Diabetes Obes Metab*. 2009;11:460-463.

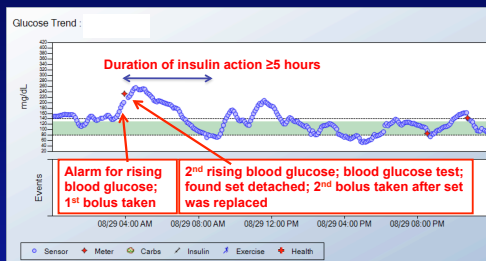
⁴ Welkymahmed ME, Litterer P, Clegg C, et al. *Postgrad Med J*. 2004;80:732-733.

⁵ Dar IH, Dar SH, Wani S. *Saudi J Med Med Sci*. 2013;1:106-108.

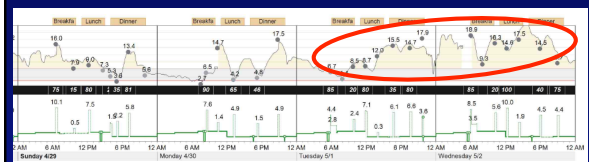
Diagnose Infusion Set Issues

- Look for UHG patterns on blood glucose meter and CGM downloads
 - Average glucose levels arranged 1 day before and up to 5 days after time of set change reveals whether pump user is having IIS issues
- Can you find a source for UHG
 - Check first for partial or complete detachment
 - Next look for blood in the line
 - Then smell for insulin leak: O-rings, hub, line
 - After removal of set, feel for a lump under skin
 - If present, squeeze to check for blood, pus, or scarring

A Full Detachment Resembles a Missed Bolus at First



Partial Detachments Are Harder to Detect



- UHG began after lunch on May 1 until late on May 2 when infusion set was changed
- "Do some highs only correct after you change the infusion set?"

Two UHGs in a Row?

Two UHGs in a Row?

Change the Infusion Set!

Do Occlusions Affect Glucose?

Occlusion Alarms Provide a Late Notification

- Long before occlusion alarm sounds, UHG will occur
- With 0.5 unit/hour basal rate in an occluded 60-cm set, time to an occlusion alarm averaged:¹
 - 1 hour, 42 minutes in Medtronic Veo
 - 2 hours, 4 minutes in Accu-Chek Spirit Combo
 - 9 hours, 10 minutes in D-Tron Plus
 - More than 24 hours in OmniPod
- Children and adults on low doses are at greater risk of having an occlusion lead to ketosis and diabetic ketoacidosis

¹ van Bon AC, Dragt D, DeVries JH. *Diabetes Technol Ther.* 2012;14:447-448.

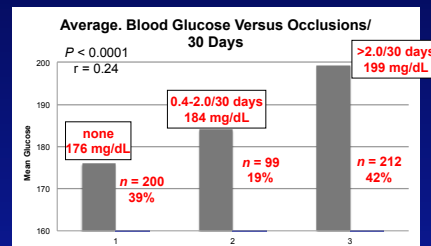
Infusion Set Issues: Occlusions

A survey of 985 insulin pump wearers in the United States and Germany found:

- 20% remembered having ≥ 1 occlusion alarm per month (23% in the United States, 17% in Germany)
- A1c trended higher for those having ≥ 1 occlusion per month (7.6%) than for those with < 1 occlusion per month (7.3%; $P = 0.09$)

Walsh J, Roberts R, Weber D, Faber-Heinemann G, Heinemann L. *J Diabetes Sci Technol.* 2015, Vol. 9(5) 1103-1110.

Frequency of Occlusions Occlusion Alarms/30 Days versus Avg. Glucose



Any occlusion worsens control

Walsh J, Roberts R, Bailey T. Unpublished data from the Actual Pump Practices study.

Does Duration of Infusion Set Use Affect Glucose? And, More Importantly, Why?

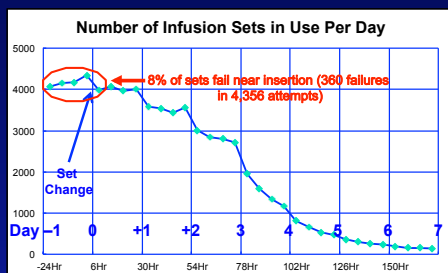
Average Duration of Use for Steel and Teflon IIS

	Teflon	Steel
Recommended use (days)	3	2
United States survey (n = 534) ¹	3.4	3.7
Germany survey (n = 451) ¹	2.8	2.6
Swedish survey (n = 102) ²	4.8	3.8

¹ Walsh J, Roberts R, Weber D, Faber-Heinemann G, Heinemann L. *J Diabetes Sci Technol*. 2015, Vol. 9(5) 1103–1110.

² Johansson UB, Adamson U, Lins PE, Wredling R. *J Adv Nurs*. 2005;51:112-118.

Actual Pump Practices Study: Duration of Infusion Set Use



Most pump wearers use an infusion set for 2-3 days

Walsh J, Roberts R, Bailey T. Unpublished data from the Actual Pump Practices study.

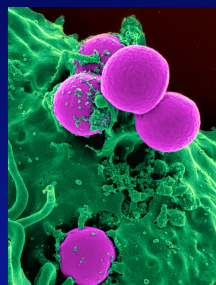
Site Infections

- Staph carriers have a higher risk of site infections
 - 30% of people are constant and 25% intermittent staph carriers
 - Methicillin-resistant staph aureas (MRSA) is common
- Requires more caution in site preparation
- Infusion site infections occur at 0.06 to 0.27 events per patient per year (30,000 to 135,000 infections per year for each 500,000 pumps)

Diabetes Care 26(4):1079-1087, 2003

Do You Carry Staph?

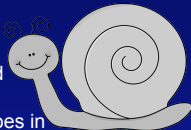
- Have you had an infusion site infection or abscess in the past?
- Has a skin cut or abrasion required treatment with an antibiotic ointment or oral antibiotic?



Improve Your Technique

Sterile Procedure

- Use clean countertop, wash hands, don't touch face or extraneous items, open packages over countertop, keep contents inside package until used, clean top of insulin bottle with alcohol
- Cleanse skin in an outward snail pattern to the size of a tennis ball and never go back (or back and forth), so cleanest spot is where infusion set goes in
- Don't blow or fan the site
- Place IV3000 bio-occlusive material on the skin under Teflon sets and over metal sets

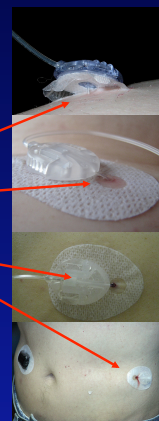


Tape the Tubing

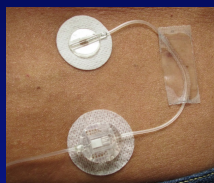
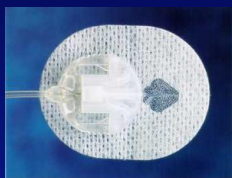
To stop:

- Tugs and pullouts
- Irritation
- Some bleeding
- Many UHG episodes

Lose tape, not insulin!



Use Low-Failure Infusion Set-Ups



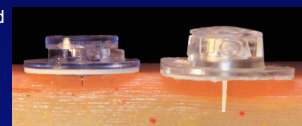
- Infusion set safety is essential for children, pregnancy (and everyone else)
- When anchored, steel sets and manually inserted, anchored Teflon sets provide greater reliability and safety ^{1,2}

¹ Renard E, Guerci B, Leguerrier AM, Boizel R. Diabetes Technol Ther. 2010;12:769-773.

² Patel PJ, Benasi K, Ferrari G, et al. Diabetes Technol Ther. 2014;16:15-19.

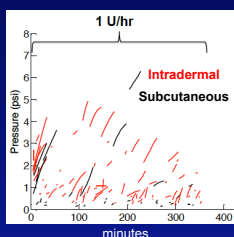
New Research – Silent Occlusions An Accidental, Significant Discovery

- BD researchers suspected infusion pressure might increase with a new intradermal sets, but not with standard sets
- Silent occlusions were seen in both
- Blood insulin diluent levels fell as line pressure rose
- Silent occlusions lasting >30 minutes were common in the first 4 hours of set use but might occur at any time
- A likely source for UHG



Pettis RJ, Hirsch L, Kapitza C, et al. Diabetes Technol Ther. 2011;13:443-450.

Unexpected Silent Occlusions with Subcutaneous IIS

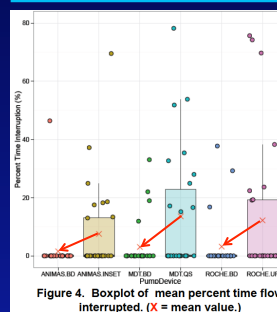


- Both intradermal and subcutaneous IIS were found to have silent occlusions
- A greater number of events were seen in the first 4 hours
- Insulin diluent is used in trial, so insulin coagulation is not involved

Graph of pressure-rise events lasting >30 minutes during first 6 hours of 1 unit/hour basal delivery (insulin diluent only)

Keith S, McVey E, Pettis RJ. Abstract #975-P. American Diabetes Association 73rd Scientific Sessions, Chicago, IL, 2013.

Dual-Port FlowSmart Infusion Set



- FlowSmart IIS compared with standard Teflon IIS in three pump brands
- ~30 insulin diluent infusions in healthy volunteers
- 74-79% reduction in percent time of flow interruptions with dual-port IIS in Animas, Medtronic, and Roche pumps, respectively

Bolick N, Morel DR, Gerth SS, et al. Poster presented at the Advanced Technologies and Treatments of Diabetes meeting in Paris, February 2015.

