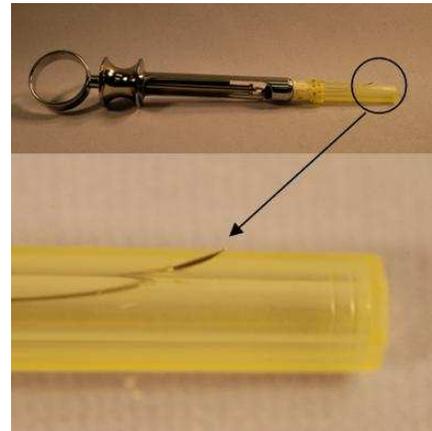


Henry Schein Inc. 27 Gauge Needle Covers (Sheaths) More Prone to Puncture (1/07)

DECS was recently contacted about a problem with Henry Schein Inc. 27 gauge needle covers being punctured by the anesthetic needle. This occurred when the dentist had bent the anesthetic needle before the injection and forcefully recapped the needle. This presented a hazard to the dental health-care provider when removing the needle/cover from the aspirating anesthetic syringe for disposal.

Single use dental needle standards (International Standard [ISO] 7885 and ANSI/ADA Specification 54) do not specify guidelines for needle cover strength or thickness. An evaluation of 27 gauge needles was conducted in the DECS Material Testing Laboratory. The results indicate that the Henry Schein 27 gauge needle covers were made of a softer plastic that displayed variable thickness. These needle covers may be more prone to puncture than other available dental needles.* Needles bent at an angle that resulted in the needle lumen oriented towards the syringe tended to bend/deform and not penetrate the sheath. However, needles bent at an angle that resulted in the needle lumen oriented away from the syringe tended to embed and penetrate the needle cover with continued force application. Extreme caution should be exercised when recapping needles that have been previously bent.

*See below for needle cover test results.



**USAF Dental Evaluation and Consultation Service (DECS)
27 Gauge Needle Cover Evaluation**

Materials and Methods

Cover Sheath Knoop Hardness: A sample of five randomly-selected needle covers were chosen from a supply of 27-gauge short dental needles from Henry Schein (Lot# 050312) and Dentsply Mil Hypo (Lot# 6706) and secured into a hardness tester stage (M-400, LECO Corporation, St. Joseph, MI). Knoop hardness measurements were accomplished using a 50-gram load with a ten second dwell time. Five hardness measurements were made for each specimen with the mean recorded as the representative specimen hardness. The mean of the five specimens was then determined as the representative hardness for the sample. An analysis of variance and Tukey post hoc tests were used to determine if significant differences existed between the products at a 95 percent level of confidence.

Cover Sheath Thickness: An additional sample of five, randomly-selected needle covers were selected from both needle groups as before. Each needle cover specimen was mounted in a low-speed diamond saw with water coolant (Buehler, Lake Bluff IL) and each tip was sectioned approximately 8 mm from the distal end of the needle cover tip. Needle sheath thickness measurements were determined at six locations to the nearest 0.0001 mm using a traveling microscope (Nikon MM-22, Tokyo, Japan) combined with a measurement device (Quadra-Chek 200, Metronics Inc, Bedford NH). The mean of the six measurements was used as the representative thickness for each sample, with the thickness mean of the five specimens used as the group mean.

Cover Sheath Strength: An additional cylinder approximately 3 mm in length of each needle cover sheath was obtained from the cover sheath thickness specimens using the low-speed diamond saw. Each cylinder was subjected to a force perpendicular to the original long axis of the sheath material using a universal testing machine (Alliance RT/5, MTS Corporation, Eden Prairie, MN) at a cross head speed of 0.5 mm per minute until either specimen failure or a force plateau was observed. Five cylinders of each needle sheath material were tested with the mean results compared with analysis of variance and Tukey post hoc tests were used to determine if significant differences existed between the products at a 95 percent level of confidence.

Results

Knoop Hardness: The mean Knoop hardness of the Dentsply Hypo needle sheath samples was 4.74 ± 0.34 while the Schein needle sheaths had a mean hardness of 3.57 ± 0.17 . Statistical analysis revealed that the Dentsply needle sheaths demonstrated a significantly greater ($p < 0.0001$) hardness than the Schein specimens.

Cover Sheath Thickness: The Schein needle sheath covers demonstrated a mean thickness of 0.7464 ± 0.1822 mm and the Dentsply samples had a mean thickness of 0.7593 ± 0.0930 mm. Although there is no statistical difference in these values ($p = 0.73$) a greater variation was noted with the Schein needle thicknesses, as the values ranged from 0.4728 to 1.0168 mm (26% coefficient of variation) while the Dentsply sheaths had a thickness that ranged from 0.5412 to 0.9660 (12% coefficient of variation).

Cover Sheath Strength: The Dentsply needle sheaths demonstrated a mean resistance to deformation plateau of 0.82 ± 0.04 MPa while the Schein specimens displayed a similar resistance of 0.74 ± 0.05 MPa. The data was found not to possess a normal distribution (Kolmogorov and Smirnov) and the Mann-Whitney U Statistic did not find a significant difference in the strengths ($p = 0.0894$).

Discussion

DECS has received reports of anesthesia needle perforation through the plastic needle sheaths of Schein 27-gauge dental anesthesia needles. This has been reported to occur on occasion after the anesthesia needles have been bent at an angle and then reinserted into the sheath. DECS was forwarded a sample box from which some of perforations were reported to occur.

Under microscopic analysis, the Schein needle sheaths were observed to present an intact surface. However, some surface pitting and porosity was noted (Figure 1) that appeared to present a more irregular surface as compared to Dentsply needle sheaths (Figure 2).

Figure 1. Schein Needle Sheath Surface (50X)

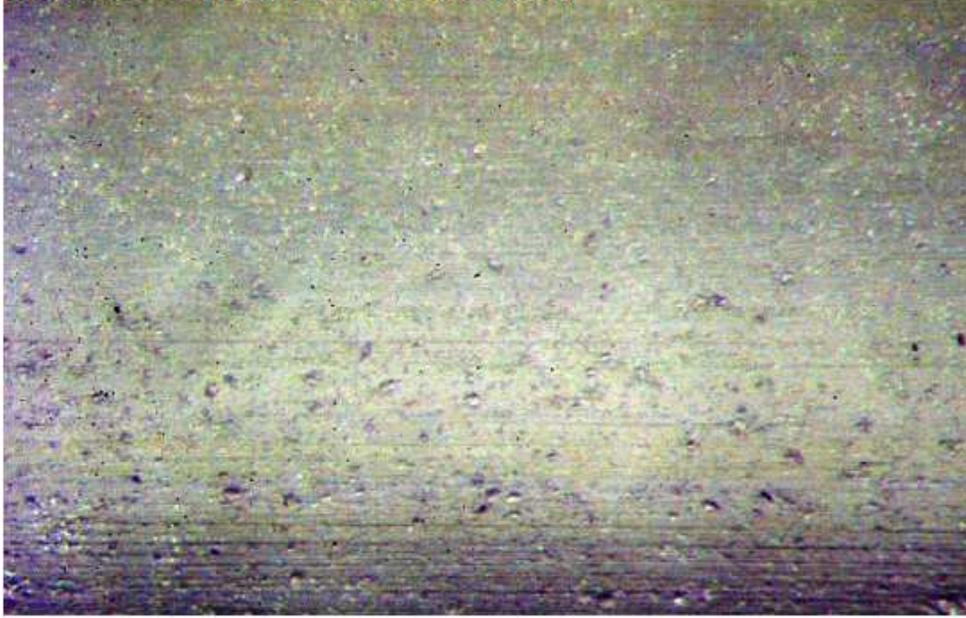
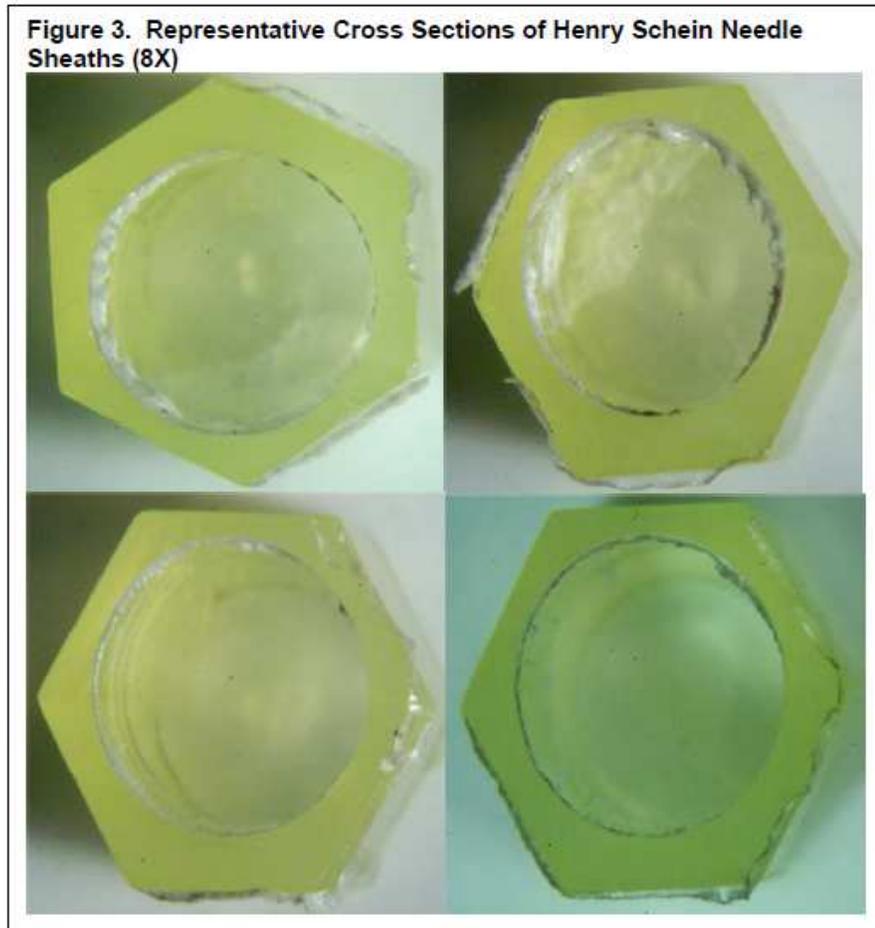


Figure 2. Dentsply Hypo Needle Sheath Surface (50X)



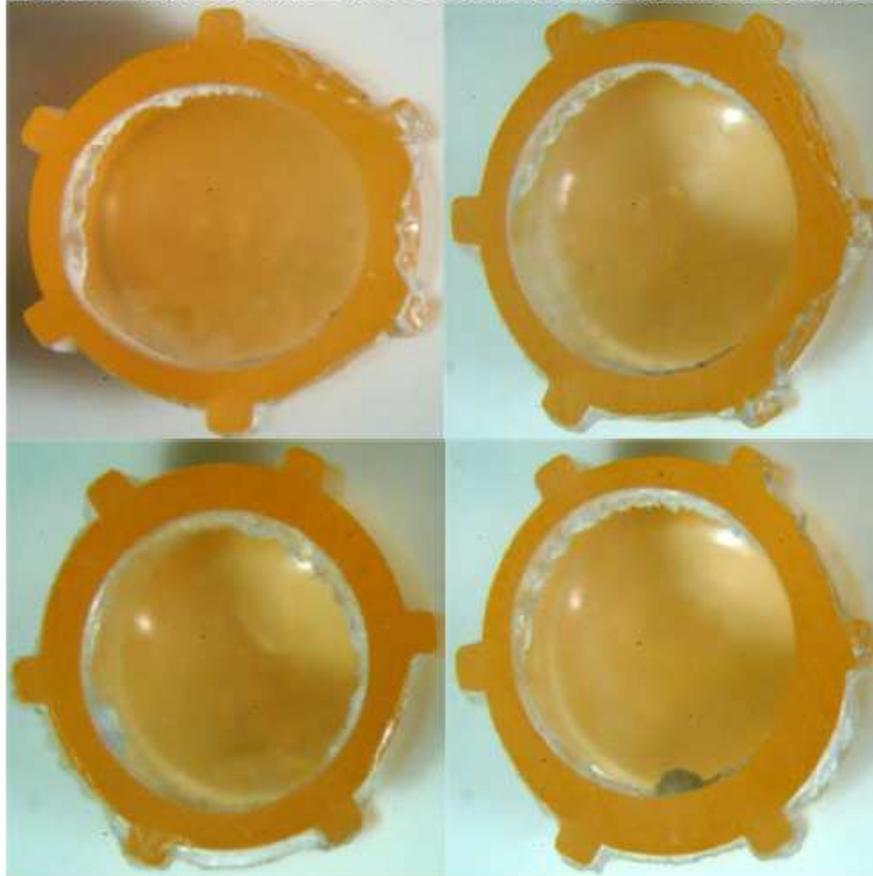
The plastic used in the manufacturer of the Henry Schein needle sheaths demonstrated a significantly lower Knoop hardness than the Dentsply product. Furthermore, analysis of the cross-sections of the different samples revealed a variation of sheath thickness. The Schein needle sheaths, when viewed in cross section, exhibited a solid plastic material in a hexagonal shape. (Figure 3)



The thickness of the Henry Schein sheaths varied in thickness. The mean thickness of the 30 measurements in the five Henry Schein specimens was 0.7464 ± 0.1822 mm. The thicknesses ranged from a minimum of 0.4728 mm to a maximum of 1.0168 mm which represented a 26 percent coefficient of variation.

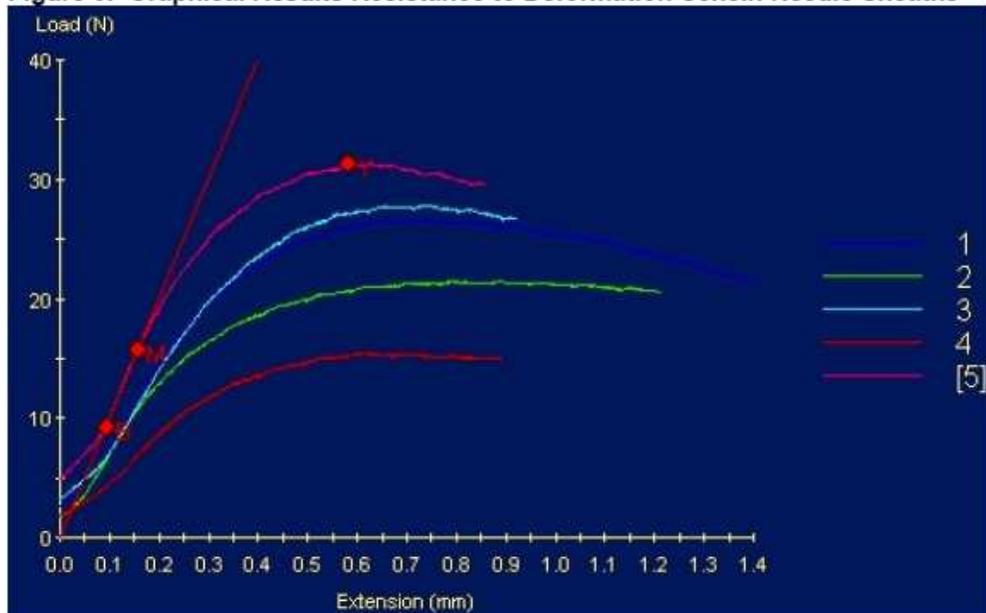
The Dentsply needle sheaths viewed in cross section (Figure 4) revealed also a solid material that was represented more of a cylindrical shape with external ribbed reinforcement. The Dentsply sheaths had a mean thickness of 0.7593 ± 0.0930 mm, which was similar to the overall thickness of the Henry Schein sheaths. Analogous to the Schein sheaths, the Dentsply sheaths also demonstrated a variation in thickness that ranged from a minimum of 0.5412 mm to a maximum of 0.9660 mm. However, the Dentsply sheaths examined had less overall thickness variation (12 percent coefficient of variation) as compared to the Henry Schein samples. Whether this reduced variation perhaps represents better quality control procedures with the Dentsply sheaths remains to be seen, for a larger sample size is warranted before more definitive conclusions can be made.

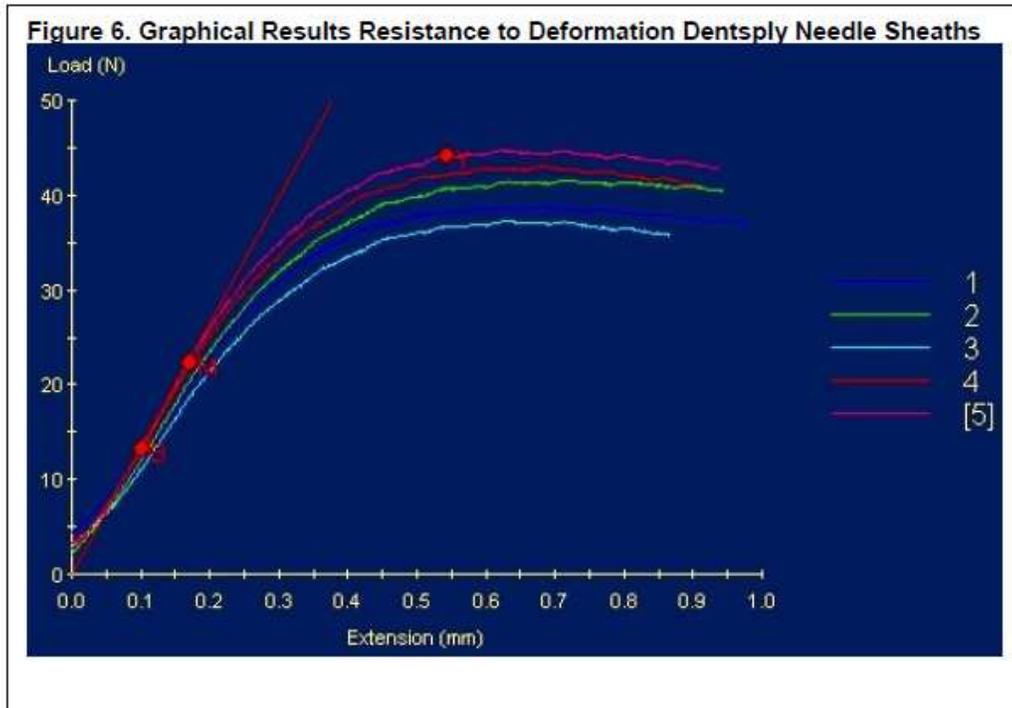
Figure 4. Representative Cross Sections of Dentsply Needle Sheaths (8X)



The final laboratory evaluation of the needle sheaths was to investigate the sheath ability to resist forces directed perpendicular against the long axis of the sheath. As can be seen in Figures 5 and 6, both the Henry Schein and Dentsply sheaths displayed a resistance to deformation that resulted in a force plateau without brittle fracture of the plastic material.

Figure 5. Graphical Results Resistance to Deformation Schein Needle Sheaths





Both needle sheaths demonstrated similar strength against deformation. The Henry Schein needle sheaths displayed a mean deformation resistance force of 0.74 ± 0.05 MPa while the Dentsply product had a mean force of 0.82 ± 0.04 MPa. The Henry Schein sample data did not display a normal distribution by the Kolmogorov and Smirnov test, and accordingly the Mann-Whitney U Statistic did not find a significant difference in the resistance to deformation strengths between the two materials ($p = 0.0894$).

Laboratory Testing Conclusions

The Henry Schein needle cover is constructed from a softer plastic that displays more variation in thickness as compared to the Dentsply needle sheath used in this evaluation. However, both needle sheaths demonstrate similar strength against deformation. Laboratory attempts to replicate the clinically-reported problem found that sheath perforation by the needle could have a higher probability with the Henry Schein product. It was especially noted that needles bent at an angle that resulted in the needle lumen oriented towards the syringe tended to bend/deform and not penetrate the sheath. However, needles bent at an angle that resulted in the needle lumen away from the syringe tended to embed and penetrate the needle cover with continued force application. Further evaluation will be required to determine the definitive force required for penetration of the plastic cover.