

SPE THE SPECIALIST

MEGATECH 2015

Tuesday, October 13, 2015 – 8:00 am - 5:00 pm

Hennepin Technical College, Room J110 – Auditorium • 9000 Brooklyn Blvd, Brooklyn Park, MN 55445

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CHOOSING THE CORRECT MATERIAL FOR THE APPLICATION AND IMPLICATIONS IF YOU CHOOSE WRONG

It can be confusing deciding if you should choose a Polypropylene, Polyethylene or TPO, how about PET, PBT or Nylon. Choosing the incorrect material can be costly for the converter and the OEM, in part failure, product reliability and field returns. We will be discussing applications ranging from Automotive to Medical and discussing how and why certain resins are chosen over the others, and cost is TYPICALLY not the contributing factor. The second half of the seminar will be going over case studies showing actual problems that customers went through because they chose the wrong material in the design stage and the hidden costs they encountered.

ABOUT THE SPEAKER – MICHAEL SEPE

Mr. Michael Sepe brings 40 years of experience in the plastics industry with a focus on injection molding, material selection, product testing, and troubleshooting. Mr. Sepe teaches public courses at several universities and writes a monthly column for Plastics Technology magazine on the application of materials analysis in solving product performance and processing problems. He has written contributing chapters for a number of industry publications and has presented over 25 Antec papers. Mr. Sepe has also authored a book on the practical uses of dynamic mechanical analysis on predicting part performance. He is currently based in Sedona, Arizona, where he runs a consulting firm with clients in North America, Europe, and Asia.



AGENDA 7:00 – 8:00 am Tabletop Setup

8:00 – 9:00 am Registration
 9:00 – noon Material selection process
 Noon – 1:00 pm Lunch is provided
 1:00 – 3:00 pm Continue material discussion
 3:00 – 5:00 pm Case study review
 5:00 – 7:00 pm Appetizers and drinks at local pub



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Late Registration: October 10 - October 13: Member: \$125 • Non-Member: \$150

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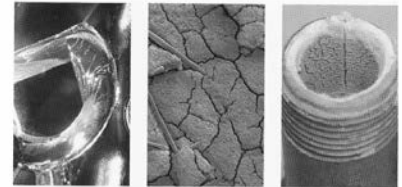
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President's Remarks *Shilpa Manjure*



Hello everyone... hope you all had a wonderful summer either going up North to your cabin or having that extra time with family!

The Upper Midwest SPE family certainly had the opportunity to connect for a day of golf this summer and like most years we had the perfect weather with clear sunny skies. Most of us hit some great shots while some others, like myself, enjoyed the company and driving around on the greens. J

Tim Morefield at Polysource and Sean Mertes at PTS walked us through the relationship between molecular weight, MFI and viscosity and its importance in relation to injection molding at our Minitch on June 23. The seminar was attended by close to 50 people. We are hoping to continue the Minitch series with focused topics of interest. Our next Minitch is on Wear and Friction of plastics in September and will be completed by the time you receive this Newsletter. Please do keep a watch out for our email announcements for future Minitchs.

Fall is time for school to begin and also time for our Student Scholarship Awards - So students please spread the word and if there is not a student chapter at your school please contact Thomas McNamara or me directly! You can find more information on application requirements and forms on our website.

Finally, we have an extraordinary one day seminar in the form of MegaTech by none other than the industry expert, MICHAEL SEPE, to be held on October 13, 2015. Please see details attached.

Looking forward to meeting you at our MEGATECH this fall!

Sincerely, Shilpa Manjure

WELCOME TO OUR NEW MEMBERS

Hamid Quraishi, Membership Chair

We are pleased to welcome our newest members of the Upper Midwest Section. As of September 10, 2015, our section has 341 active members! Tell your friends and co-workers about the SPE Upper Midwest Section to help us grow and check out our website, www.uppermidwestspe.org, and the national website, www.4spe.org, to know all that SPE and this section has to offer

New Member

Jacob Sullivan

Raymond Meldahl

Affiliation

UW Stout, Menomonie, WI

ES Plastic Products, Waterford, WI

UPPER MIDWEST SPE HOSTS THE ANNUAL GOLF TOURNAMENT

Another Upper Midwest SPE golf tournament has come and gone and it was another great year at the Oak Marsh golf course. We had a beautiful day and a great turnout this year with several new faces joining us this year, special thank you to those that traveled a long distance to join us. Your support is very much appreciated. The winning team this year was team Nexeo (Todd Betterley, Joel Jenson and their guests) shooting a 62 for 8 under par. We also had a special game of ring toss to win an iPad after the round which John Denney won. Without our great sponsors (Nexeo Solutions, Amco, PolySource, Polymer Technology and Services, Incoe, American Injection Molding Institute, and Clariant) none of this would have been possible we would like to send them a special thank you as well. Next year's Upper Midwest SPE golf tournament will be Tuesday August 2, 2016. Please mark your calendar.



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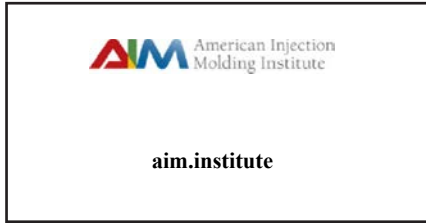


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SCIENCE CORNER

DESIGN AND CHARACTERIZATION OF PLASTIC HYPODERMIC NEEDLES

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Abstract

This paper presents the design, fabrication, and testing of a prototype plastic hypodermic needle. Experimental penetration tests using plastic and steel hypodermic needles with rubber skin mimics, specifically polyurethane film, and with pig skin were performed to determine penetration and friction forces, and resistance to repeated bending. Tests were conducted to determine fluid flow rates through the needles. Finite element analyses were performed and compared to experimental buckling tests.

Introduction

Significant potential for plastic hypodermic needles exists as an alternative to current steel needles, especially in developing countries where proper needle disposal is problematic. Needle reuse causes tens of millions of hepatitis and HIV infections each year [1]. Plastic needles may reduce the reusability aspect and increase the opportunities for safe disposal. Plastic needles also will facilitate medical waste disposal by removing metal from the waste stream, hence making it easier to recycle needles and syringes into useful products such as car battery cases and pails. Previously, prototype plastic hypodermic needles were produced and tested [2, 3]. These were fabricated by injection molding using a metal wire core with their hole at the end of their cannula, and were approximately 25 mm long.

Materials and Fabrication

The plastic needles studied for this paper were manufactured with 38.1 mm length, 0.72 mm diameter at the tip, tapering outward over the length of the cannula to a diameter of 1.2 mm at the hub, and a 70% ID/OD ratio (Figure 1). Unique features of the needle are that it is tapered, which is not easily possible with a steel needle and leads to a more efficient mechanical design, and that its hole is on its side rather than at its tip, which allows for a solid, stronger tip and reduces coring of the rubber vial stoppers which can contaminate the vaccine or medicine. The plastic material utilized is Ticona Vectra 1300MT, an unfilled medical grade (USP class VI) liquid crystal polymer (LCP). LCPs feature a higher modulus and strength than traditional plastics, and have the unique feature of an increase in strength as the wall thickness decreases [4]. They also

have good properties when subjected to creep and fatigue. LCPs can be easily molded, which is advantageous for creating large numbers of parts at relatively low cost. The needles are manufactured using a gas-assisted injection molding (GAIM) process. The design of the needles has not yet been optimized for minimum penetration force, as the needles are still in the prototype phase.

Finite Element Analysis

Finite element analyses (FEA) were performed to study the buckling behavior of the plastic needles. The tests were performed using ANSYS Workbench version 11.0. Solid models were generated based on the shape of the needles, and the end conditions were chosen to reflect those present when a needle penetrates the skin. In the model, the hub was fixed to prevent displacement and rotation. The tip was given a fixed displacement during the simulation, with motion allowed only in the direction of the needle's longitudinal axis as well as free rotation about any axis. These constraints on the movement of the needle replicated its motion during initial contact with the skin. The FEA conditions and results are summarized in Table 1. For comparison, two tip conditions were simulated – sharp tip and blunted tip. This allowed one to determine the effect of the presence of the tip on the results when compared to experimental buckling tests. Also, two different cross-sectional shapes were studied because the actual needles had elliptical cross sections.

The buckling simulations showed many trends concerning the effect of the variables. The tapered needles had a buckling strength 125-175% greater than the straight needles of the same length and cross section at the tip. One interesting phenomenon was found with the changes in the cross sections. For tapered needles, an elliptical cross section had a buckling strength 14-17% lower than the round cross section (here the major axis of the elliptical cannula was the same size as the diameter of the cylindrical cannula). However, for straight needles, the opposite trend existed; the buckling strength was 1-2% higher than the tapered needle's strength. Changing the length also had a large effect on the buckling strength. Reducing the length from 38.1 mm to 25.4 mm increased the strength 98-120%. The needles tested for this paper were tapered with an elliptical cross section. The FEA suggests that buckling would occur from 3.2-6.7 N for 38.1 mm long needles and from 7.3-13.4 N for 25.4 mm long needles.

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Buckling and Penetration Tests

Buckling tests with fixed-fixed end conditions were conducted by forcing a needle vertically against an aluminum plate at 60 mm/min using an Instron model 4466 testing machine. Side motion of the needle was prevented by a small notch in the aluminum plate. These tests were performed to confirm the finite element analyses of the buckling performance of the plastic needles. The tests showed that buckling occurs at axial force levels of between 4 and 6 N for 38.1 mm long needles, and between 10 and 12 N for 25.4 mm long needles. These results are within the ranges that the FEA predicted. The buckling tests provided a target value for the needles' maximum penetration force.

Penetration tests were performed using the plastic needles with cannula lengths of 38.1 mm and 25.4 mm, and their performance was compared to that of 22 gage steel needles of length 25.4 mm. The shorter needles were created by cutting off the hub, leaving the tip end intact, and gluing the desired length into a new polypropylene hub. The tests were performed on an Instron model 4466 testing machine. Tests were performed at a speed of 100 mm/min and an exposed rubber area of 506.5 mm² based upon a study of manufacturers' internal testing protocols and international standards (ISO 7864 [5], ISO 9626 [6], DIN 13097 [7]). These are comparable to the insertion speed found in practice and the area of skin affected by a needle penetration. These conditions were used for all of the penetration tests conducted for this paper.

The skin mimic used for the penetration tests was polyurethane film (McMaster-Carr #1446T41, 0.37 mm thickness), which was consistent with DIN 13097. The rubber skin mimic was supported horizontally in a fixture and was elevated to allow the needle to penetrate. The needle was attached to a 25 N load cell suspended from the crosshead, as shown in Figure 2. Previous characterization tests showed that there was no significant difference in penetration forces for changing speeds or exposed rubber areas; thus, the tests were performed with those variables held constant.

Steel hypodermic needles are coated with a silicone lubricant; one commercial lubricant is Dow Corning MDX4-4159, 50% silicone medical grade. The MDX4-4159 is a silicone dispersion that chemically bonds to steel needles, keeping them lubricated until use. The original, as-received dispersion consists of 50% silicone oil-based material mixed, with the bulk of the material being a solution consisting of 70% mineral spirits and 30% isopropyl alcohol. For the final lubricant, the necessary final silicone component content is <5%, so the original solution was diluted using a 70% mineral spirit, 30% isopropyl alcohol mixture to obtain the desired silicone component content. The lubricant was coated onto the plastic needles using the manufacturer's recommended conditions at 2.5% and 5% silicone content. One should note that the lubricant was developed for steel, not for plastic; so adequate adhesion was not guaranteed.

A typical graph of a penetration test is shown in

Figure 3. In it, the penetration force is the load required to puncture the test sample; the friction force is the load required to continue to move the needle through the sample. The results for these penetration tests are summarized in Table 2. The test results show that a 5% silicone content coating enables a greater penetration percentage than 2.5% silicone content. On average, 20% of the lubricated needles at 38.1 mm length coated with 5% silicone content dispersion were able to penetrate the polyurethane. These numbers increased to 50% penetration for 25.4 mm length needles due to a reduction in buckling. These results demonstrate that the lubricated plastic needles are capable of penetrating the polyurethane skin mimic. These results are encouraging, as neither the needle tip geometry nor the lubricant was optimized. In light of these results, future work will focus on optimizing both.

As a benchmark, steel needles (Kendall Monoject Polypropylene Hub Hypodermic Needles, #250222, 22 gage, 25.4 mm length) were tested in the same manner as the plastic needles. They were tested as-received (with lubricant) and with the lubricant removed (by KOH and IPA). The penetration forces were lower for the steel needles than for the plastic needles, and removing the lubrication increased both the penetration force and the friction force. The penetration forces for lubricated steel needles ranged from 0.5-0.6 N, and the friction forces ranged from 0.06-0.1 N. These results are summarized in Table 3. Comparatively, the penetration forces for unlubricated steel needles ranged from 0.9-1.7 N, with friction forces from 0.3-1.2 N. This is expected, as the steel needles are stiffer than the plastic ones, and benefit from many years of tip design optimization to reduce penetration force.

Pig Skin Tests

Tests were performed using the plastic needles to penetrate pig skin to simulate human skin. Pig skin should be a better indicator than rubber of how the plastic needles will penetrate human skin. The pig skin was stored frozen and was defrosted on the morning of the test by submersion in a cold water bath until it reached an appropriate temperature. The skin sample consisted of the skin layers as well as a layer of fat immediately beneath the surface of the skin. The skin was mounted in the test apparatus in a similar manner to the polyurethane film, and the tests were performed according to the same protocol.

The plastic needles tested were 25.4 mm long and lubricated with the 5% silicone content lubricant. Four needles were tested; three successfully penetrated the pig skin. The penetration forces for the three successful tests were 6.5, 9.3, and 9.5 N, and the needle that failed to penetrate the skin buckled at 8.9 N. These results, summarized in Table 4, are similar to those achieved in the tests into the polyurethane film. Again, the lubricated steel needles were tested for comparison. Their penetration forces ranged from 0.8-1.2 N, which are higher than the forces achieved during the polyurethane penetration tests. This presents a contrast to the plastic needles of the same length, which performed better

in the pig skin than in the polyurethane.

Perpendicular Force Tests

The perpendicular force test, outlined in ISO 9626 - Annex D, was used to test the plastic needle's ability to withstand breakage when a fluctuating load is applied at the tip perpendicular to the axis of the cannula. This test was performed on the Instron testing machine, with the needle supported from its hub, extending horizontally. A piece was attached to the crosshead which enabled the needle to bend vertically as the crosshead was moved. The test setup is shown in Figure 4. The needles were bent 25° from the horizontal in each direction, creating a 50° included angle, over 20 complete cycles. The needles did not break during this test due to the flexibility of the LCP, and thus passed the test.

Fluid Flow Tests

Fluid flow tests were performed on the needles. The test was performed by affixing a syringe to the base of the Instron testing machine with the plunger extending upwards. The load cell was forced down onto the plunger, expelling the liquid (in this case, water) while measuring the force required to push the plunger. Two different syringes are used, with volumes of 1 ml (Becton- Dickinson 1 ml Luer-Lok Syringe, #309628) and 3 ml (Becton-Dickinson 3 ml Syringe, Slip Top, #309586), and two speeds were tested, 20 mm/min and 200 mm/min. The full-length plastic needle (38.1 mm) was tested, as were steel needles and syringes without a needle.

The results are summarized in Table 5. They show that at 20 mm/min, forces of 0.1-0.5 N are necessary to depress the 1 ml syringe, while 0.8-1.5 N are needed for the 3 ml syringe, with an initial force slightly higher. These results depend on the syringe, and the needle had no effect on these values. For each of the three conditions (plastic needle, steel needle, no needle), the forces that both the smaller syringe and the larger syringe require to expel the water were statistically similar. This indicates that the plastic needles are equally capable of expelling liquid as compared to the steel needles at 20 mm/min.

However, at 200 mm/min, the forces required to depress the syringes increased, and they become dependent on the presence of a needle on the syringe. Without needles, forces of 0.6-0.9 N are necessary to depress the 1 ml syringe, and forces of 1.6-2.3 N are required for the 3 ml syringe. The 1 ml syringe can be depressed with 0.8-1.4 N of force with either type of needle attached, while the 3 ml syringe required 2.1-3.0 N with steel needles attached and 3.3-3.8 N with plastic needles. Thus, the plastic needles do not perform differently from the steel needles on the 1 ml syringe, but the forces are higher for the 3 ml syringe. These results show that the plastic needles perform similarly to the steel

needles for the delivery of water. There are no required values for the force to empty a syringe-needle combination. The recommended values for filling the syringe-needle combination are 10 N to initiate plunger movement, and 5 N average value according to Annex G of, ISO 7886-1 [8] and WHO standards [9]. So, the experimental values should be acceptable without modification of the needles. Of course, these values may be lowered by changes in the bore of the plastic needles.

Conclusions

These experiments studied the penetration of lubricated plastic needles into a rubber skin mimic and pig skin. The results of finite element analysis simulations were confirmed by buckling tests. Supplemental testing performed on the needles showed their resistance to breakage in bending. Additionally, fluid flow testing showed that fluids can pass through the plastic needles comparably to the steel needles. These results show that plastic hypodermic needles show excellent promise as replacements for steel hypodermic needles. The needle tip geometry and the lubricant both should be optimized to further reduce the penetration forces.

Acknowledgments

This work was supported by SS&B Technology, Australia, which also fabricated and supplied the plastic needles.

References

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- [5] ISO 7864:1993(E) Sterile Hypodermic Needles for Single Use.
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- [9] WHO/EPI/LHIS/97.11 Equipment performance specifications and test procedures - E8: Injection devices, World Health Organization, Geneva, 1997- Updated 1 January 1998.

Length (mm)	Cross-Section	Taper	Sharp tip, load (N)	Blunted tip, load (N)
38.1	Circular	Tapered	7.9	4.9
38.1	Elliptical	Tapered	6.7	3.2
38.1	Circular	Straight	2.9	1.7
38.1	Elliptical	Straight	2.9	1.3
25.4	Circular	Tapered	15.6	11.1
25.4	Circular	Straight	6.4	4.1
25.4	Elliptical	Tapered	13.4	7.3
25.4	Elliptical	Straight	6.4	3.1

Table 1 - Buckling FEA Results

Solution	Cleaned	Length (mm)	Avg. Penetration Force (N)
5%	N	38.1	3.0
5%	Y	38.1	3.7
2.5%	N	38.1	3.3
2.5%	Y	38.1	3.5
5%	N	25.4	6.9
5%	Y	25.4	8.3
2.5%	N	25.4	6.0
2.5%	Y	25.4	10.0

Table 2 - Penetrations with Lubricated Plastic Needles in Polyurethane

Lubricated	Average Penetration Force (N)
Y	0.5
N	1.3

Table 3 - Penetrations with Steel Needles in Polyurethane

Needle	Lubricated	Length (mm)	Avg. Penetration Force (N)
Plastic	Y	25.4	8.4
Steel	Y	25.4	1.0

Table 4 - Needle Penetrations in Pig Skin

	No Needle	Steel Needle	Plastic Needle
1 ml syringe			
20 mm/min	0.1-0.3	0.1-0.5	0.2-0.5
200 mm/min	0.6-0.9	0.8-1.4	0.9-1.3
3 ml syringe			
20 mm/min	0.7-0.9	0.6-1.1	0.9-1.5
200 mm/min	1.6-2.3	2.1-3.0	3.3-3.8

Table 5 - Fluid Flow Testing Results (Forces in N)



Figure 1 - 38.1 mm LCP needle

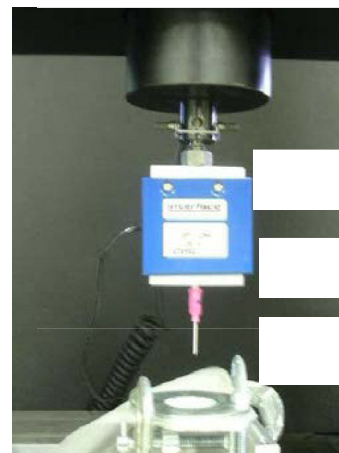


Figure 2 - Penetration Testing Setup

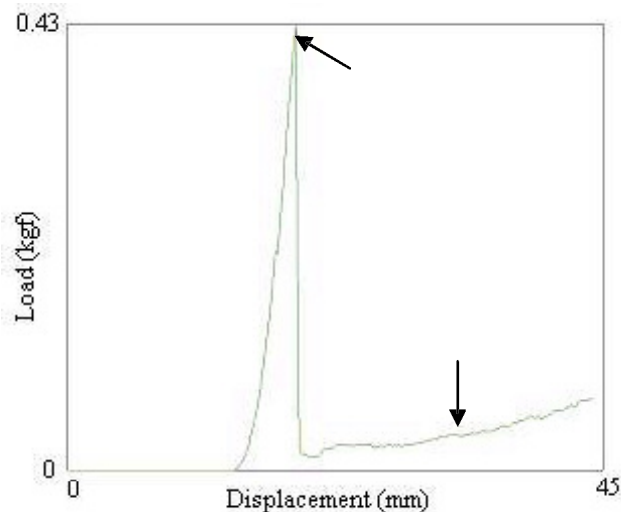


Figure 3 - Successful Penetration Test Result

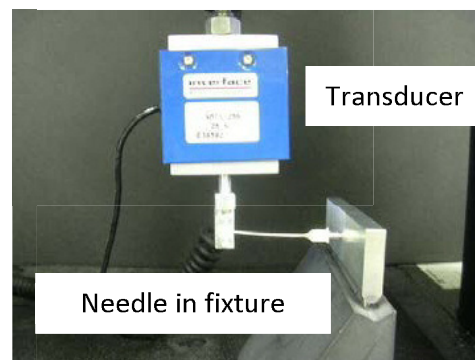


Figure 4 - Perpendicular Force Test Setup

Councilor's Corner

Tom McNamara - Councilor - Upper Midwest Section

We have not had a Council meeting since our last SPEcialist was published. However, the Executive Committee has been active with several meetings since then. Some of the items being discussed by SPE staff and the EC are:

Much discussion on the governance of our Society. The governance model we are using today is the same that we have had for several decades. Discussion evolves around optional models that should be considered to make our Society more effective at serving our membership. Benchmarking of other societies is taking place.

A fair amount of discussion about Section / Division rebates has transpired. Establishment of a 'Rebate Payment Day' after which a Section or Division would forfeit its rebate for that quarter is being assessed.

Clarification of consequences / penalties when a Group does not file the IRS forms as required.

More stringent track record of communications from the Groups. SPE HQ will be adding a column to the Excel forms we use. The column entitled "Last Heard from" will automatically renew when a change is made anywhere else on the form.

Much discussion has been taking place concerning the requirements for a Section or Division to receive a Pinnacle Award. One requirement being considered is a KPI based on the ratio of Students and Young Professional members to Professional members. Another KPI would be the ratio of Young Professionals to Professionals on the Group's Board of Directors.

Discussion about staffing needs at SPE HQ to meet future needs to take care of sales, international, operations, events, marketing, and communications.

Most likely a bylaw change will be proposed to Council to eliminate the remote participation for Council meetings. Remote participation had been implemented several years ago to allow more of the International Sections and Divisions to participate in the Council meetings. However, due to the low participation (primarily because of the time zone differences in Europe and Asia) and the expense for providing the remote participation, it is felt there was not enough of a cost benefit.

Discussion of the SPE Chain indicated that the activity is slower than expected. Additional education, especially about the many features, is probably necessary.

Our next Council meeting is scheduled for October 9, 10, & 11, 2015 in Pittsburg, PA

SPE Education Committee - *Tom McNamara*

A special arrangement has been made with the SPI organization to subsidize student SPE dues. Student membership dues will be waived and SPI and SPE would share the membership cost for each student taking advantage of this offer.

Students receive free membership to SPE (Society of Plastics Engineers) and an electronic membership to SPI (Society of Plastics Industry) yearly when they join SPE or renew! **Students who are US Citizens with primary residency in the US** receive their complimentary membership by simply joining **or** renewing online.

Make sure you take advantage of this offer as it does expire December 31, 2015.

Once again our Section is offering scholarships to students in plastics related studies in both 2-year and 4-year programs. The 2-year students should be applying for the Tony Norris scholarship award while the 4-year degree students should apply for the Jerome Formo scholarship award. Please check the Upper Midwest Section website for requirement and application links.



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October 2015

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CALENDAR OF EVENTS

- FALL MEGATECHOctober 13, 2015
- AWARDS CEREMONY.....January 30, 2016
- BIOPLASTIC MATERIALS TOPCON.....April 19-21, 2016
- ANTECMay 23-25, 2016
- ANNUAL GOLF OUTINGAugust 2, 2016

Upper Midwest Section (s22) Membership

September, 2015

Section Total 341