





## Message from the Head office

#### National President's Message



Dear Members,

I am glad to know the editorial team are brining 2nd edition of ADITI newsletter. It is true printing media gives lot of information to fellow members. No doubt, these days many are depending on digital media. Different groups circulating wanted and unwanted messages among themselves. I am lucky I don't use mobile many times I have been misquoted with regards to various trade shows.

I would like to make it very clear at this point of time through this newsletter my stand is crystal clear, all time my top priority is for ADITI trade shows. I am committed, I have conviction to take ADITI to greatest heights, it may be Expodent or any other trade activities like manufacturing, importing, trading anything. I explained to all my team members to do business ethically as various rules and regulation are coming up for dental equipment, materials, instrument and implants. At this point of time it is responsible and gear up ourselves for this challenge. Many times people take my name for their convenience but let me make my point clear, I am not against any trade fair conducted by anyone. I always believe that people should decide which is good for them, their business and where they are wasting their money. There are many exhibitions becoming absolutely commercial and it has become money making machine. They are least concerned about exhibitors as far as exhibitors pay money they are happy. So my only appeal was to be selective with regards to your participation. If you feel particular exhibition is going to fetch you lot of business please go ahead, you should never listen to anyone. You should not take part just for competition sake. There are so many exhibitions so many conferences it is unthinkable. If you go on participating, selling product at discounted rate and spending money your balance sheet might go in red.

So that is only message I have circulated to be cautious but some people I understand they are lobbying against particular company, to be precise Famdent. I don't understand great association like ADITI why we should be scared for anyone, we are leaders, and we shall stay as leader. The way I understand message is coming around shows our weakness. Please refrain from all these things. I don't believe in such things, I always believe we should grow to stronger, making life stronger by drawing a big line adjacent to that, not by cutting line. There are many in the association are trying to cut the line which is absolutely unethical activities. You should make your every exhibition greatest one in the country.

I look forward for all of your cooperation and refrain from unwanted activities, unwanted messages circulating in digital media. If there is any issues we shall discuss in forth coming CEC and come to conclusion with regards to our course of action. I appeal and request each and every member to stop unwanted circulation.

With regards,

DR. B. SUBHASCHANDRA SHETTY



## Message from the Editor



Dear Colleagues,

It was my pleasure and great privilege to present the introductory issue of the ADITI News. The editorial team and myself are overwhelmed by the appreciation received from the members.

We believe a well functioning association requires well-informed members. So our mission is simple: to provide you with a reliable source of high quality, evidence-based information. With this mission in mind, in this issue we highlight the various committees set up by the head office for the benefit of the members, the association and the dental industry as a whole. We also offer a glimpse into the various activities of all the zones. Furthermore we are publishing an article that highlights the various compliance and regulations in force currently and its implications for our members.

With this issue we attempt to provide the reader with a new, well constructed, informative, and educational magazine. The entire editorial board and I encourage you to submit unique and enlightening articles and whole-heartedly support our magazines with your advertisements.

Best Regards, Biren Patel

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## **National Updates**

The venue for the constitution committee meting on 31st August 2018 and the second CEC meeting held on 1st September 2018 was Hyatt Place, Hyderabad.

At the CEC, Mr Rajnish Verma made a presentation on the existing and upcoming regulations with regards to registration with the CDSO and the gray areas that need to be addressed with regards to the same. Mr. Vishal Anand discussed the possibility of an ADITI Indian pavalion at the IDS in Germany. Mr. Biren Patel reported that the official email addresses for the key office bearers were created and urged all to use only these for all communications related to ADITI. The first issue of the ADITI News was officially released by the office bearers.









presented a report on the Expodent held in their respective zones. Mr. Rajinder Mathur shared details of the upcoming Expodent International India

The National office bearers are also pleased to announce the opening of the ADITI office in New Delhi at C-111, Ground Floor, Lajpat Nagar Part-II, New Delhi-110024. This office will now be used as a base for all operations of ADITI and will also be the official address for all communications to and from the head office.

The office bearers are also pleased to inform the members that work on a state of the art ADITI office in Bengaluru is aslo under way. After a pooja ceremony the work has been progressing smoothly.



Mr. Shammi Gumbhir, Honorary Secretary of Association of Dental Industry & Trade of India was invited as the key Panelist for DST- CII India Italy Technology Summit held on 30th Oct'2018 at Hotel Taj Palace, New Delhi. His speech was oriented towards the robust Indian-Italian cooperation in technology intensive business in Healthcare sector.

The Panel discussion session was later addressed by the Honourable Prime Ministers of India and Italy – Mr. Narendra Modi and Mr. Giuseppe Conte respectively. They also spoke on innovative ways to boost cooperation in key areas of technology trade including Healthcare.





## National Updates

#### **List of Committees**

**ADVISOR Ell and Central Observer** Mr. Rajiv Seth

#### **Ell Core Committee**

Mr. Rajinder Kumar Mathur	
Mr. Firoz Merchant	
Mr. R K Jain	
Mr. Sanjay Aggarwal	
Mr. Rajiv Seth	
Mr. C J Shastry	
Mr. Dilip Valimbe	
Mr. Karan Bir Suri	
Mr. Mantu Chowdhury	
-	

Mr. Ajay Jayna Mr. Anil Mathur Mr. Anil Seth Mr. Ashok Goel Mr. Atul Kaushik Mr. Harish Arora Mr. Rahul Khanna

Chairman Co-Chairman Co-Chairman Co-Chairman Advisor Vice President Vice President Vice President Vice President

LOC Member LOC Member LOC Member LOC Member LOC Member LOC Member LOC Member

#### **Committee for International Investor Meet**

Mr. Vishal Anand	Convener
Mr. Amitabh Sachdeva	Member
Mr. Kanwal Jit Singh	Member
Mr. Karan Bir Suri	Member
Mr. R K Jain	Member
Mr. Rajesh N Bhojwani	Member
Mr. Rajnish Verma	Member
Mr. Sameer Baldota	Member
Mr. Satinder Singh Grewal	Member

#### Committee to Represent and Guide all Members related to Government Guidelines

Mr. Rajnish Verma	Convener
Mr. Amitabh Sachdeva	Member
Mr. Bharat Thakker	Member
Mr. J. Vijay Kumar	Member
Mr. Mikil Baval	Member
Mr. Praveen Malhotra	Member
Mr. Sanjay Goel	Member
Mr. Sanjiv Puri	Member

#### Committee for recommending changes in ADITI Constitution

Mr. Bharat Thakker Dr. Deepesh Bagadiya Mr. Harish Arora Mr. K. Udayaraj Shetty Mr. Manash Chowdhury Mr. Praveen Malhotra Mr. Rajinder Kumar Mathur Mr. Uday Patel Mr. Vinod Baval

Mr. Ajay Singhal

Member Member Member Member Member Member Member Member Member

Convener

#### **Editorial Committee**

Mr. Biren Patel	Convener
Mr. Ajay Singhal	Member
Mr. Amitabh Sachdeva	Member
Dr. Bhavin Patel	Member
Mr. Karan Bir Suri	Member

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## **Zonal Updates**

North Zone The North Zone has been very busy of late with many activities buzzing around us. The Second ZEC of the North Zone took place on 22nd of August 2018 in New Delhi. Many issues pertaining to the functioning of our Association were discussed. There have been TWO New Appointments in our North Zone. I feel very pleased to inform all of you that Mr. Vinod Sethi has been appointed the Chairman for EXPODENT North Zone and that Mr. Ashu Shrivastava of M/s Unique Dental has been appointed as the Zonal Joint Secretary.

The North Zone started a campaign and successfully contributed approximately Rs.450,000.00 (Rupees Four Lakh Fifty Thousand) to the Kerela Chief Ministers Relief Fund.



Expodent North Zone was held on 15-16th of September 2018. Many new changes in the working of this Expodent were made. Booths were allotted ONLY to ADITI Members with a limit of TWO Booths Only. With the able guidance of Head office Bearers, Chairman, Advisor and the Entire Organizing Team, Expodent North Zone has broken all previous records.

The zone also held a Seminar for all Exhibitors and ADITI Members at Hotel Ramada at Zirakpur in conjunction with the Banquet to give Members a fore view of matters which our Members may face at the time of importing goods which are now coming under the stringent CDSCO Laws. Around 80 Plus Members / Exhibitors attended the Show. There was a one to one meet also organized. Almost all Members Exhibitors appreciated the new approach of the North Zone in educating Members.



North Zone







North Zone also organized a Diwali Get Together on 29th October 2018 at CAFÉ OMG, Connaught Place. The entire Restaurant had been booked for the Occasion. The memberd had the lighting of the ceremonial Diya and then later enjoyed Live Music followed by Dinner.







## **Zonal Updates**

#### West Zone

The West Zone organised it's third ZEC at Pune on 4th August 2018 with the National President, Dr. Shetty as special invitee. The morning meeting concluded with Lunch for all the attendees.

The West Zone Expodent was organised at NESCO, Mumbai on 20-21 October 2108. The Organising team was a great mix of senior experienced members and young and dynamic members.

The show had over 300 booths and attracted over 4000 national and international Visitors. As a first the Mumbai Expodent organised an Exclusive ADITI Lounge for all ADITI Members to relax and also conduct metings in a comfortable manner with complimentary refreshments.







### South Zone

Expodent Bengaluru was the highlight event for the South Zone. The expodent was held at the Banglore International Exhibition Centre on 4 - 5 November 2018.

The show hosted by an experienced organising team under the guidance of central office bearers had more than 200 companies with over 450 stalls.





## **Expert Communique**

#### An Overview of Regulations for Dental Products / Devices in India under GSR 78EIn India

The Medical Devices are getting Regulated under CDSCO (Central Drugs Standard Control Organization). CDSCO is the Apex Regulatory Body under Ministry of Health and Family Welfare in India. The Medical Devices Originally were Regulated Under Drugs and Cosmetics Act of India 1940 and Rules 1945 Thereunder. In 2005 the Regulation for Medical Devices was implemented. On 31st January 2017 the New Medical Device Regulations were published and they have become effective from 1st January 2018. Title of These Regulations is GSR 78E It means many medical devices including Dental Products / Devices have come under these regulations.

**Positive Point about These Regulations:** These Regulations are definitely going to be enforced but in a Phase Manner. That means that These Regulations will not be enforced on all Medical Devices in Single Enforcement, rather gradually including more and more products under These Regulations through Gazette Notification. CDSCO Will publish the list of Notified Devices from Time to Time.

However, as These Regulations are already published for Indian Manufacturers and Foreign manufacturers, the Dental Products that have been included so far in the list include:

- Dental Implants and Abutments
- Bone Grafts and Membranes
- Orthodontic Wires

Out of the above-mentioned dental devices, the Dental Implants and Abutments, Bone Grafts and Membranes were already requiring License for Import or Manufacture in India.So, Orthodontic Wires have come under These Regulations, however when we see the description of the Orthodontic Wires: A wire conforming to the alveolar or dental arch that can be used with dental braces as a source of force in correcting irregularities in the position of the teeth. So It means that dental braces / brackets are already covered.Still if there is any clarification required, the formal information can be obtained from CDSCO.

CDSCO has classified all Medical Devices including dental devices as:

Class A, Low Risk Devices: Like Dental Chair Units,

Dental Overhead Lights, (Not Yet Mentioned in the list)

Class B, Moderate Risk Devices: Like Orthodontic Wires

Class C, High Risk Devices: Like Dental Implants, Bone Grafts, Membranes,

Class D, Highest Risk Devices like Coronary Stents, Knee Joints, Hip Joints.

The time that will be taken to include more products can be assessed by considering that so many high risk and highest risk devices like Pacemakers, CT Scan, MRI, Ultrasound, X-ray are yet to be notified. So it seems that the addition of many class A, and Class B dental devices will take time.

The affected Business Organizations that deal in These Regulated Dental Devices are:

- 1.Indian Manufacturers
- 2.Foreign Manufacturers
- 3.Indian Distributors
- 4.Indian Retailers.

The licenses that are applicable on these Business Organizations are:

1. Manufacturing License for Indian Manufacturers

2.Loan License for Indian Traders who are willing the Original Licensed Manufacturers to manufacture under their own brand name.

3.Import License for the Indian Distributors who are willing to import these devices from foreign manufacturers.

4.Retailers may continue to sell the devices just like previously.

IMPORTANT: If a company is only Distributing or Only Doing Retailing, they can import from foreign manufacturer registered in India or purchase from domestic licensed manufacturer, however It is Illegal to purchase the bulk devices and pack in an unlicensed premises without approval of the facility to the re-packing and re-labeling.

We Welcome the Questions and Clarification Requirements from ADITI.

Shri Kant Tiwari

Director: DKNSB Medical Device Consultants



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## Tech Speak

## **Orthodontic brackets : Manufacturing processes**

The word Orthodontics is derived from a Greek word orthros meaning straight and odontos meaning teeth. The main goal of this treatment procedure is to improve oral functions, aesthetics and general dental health for the patients. Orthodontic braces were not invented until the early 1800's but desire for straight teeth could also be seen during that period. Archaeologists discovered many mummified remains in and around Egypt. It was also found that some teeth of deceased had gold wires wrapped around the teeth for space closure.

The first official use of the word "braces" was in the early 1900's. During this time the dentist use to wrap metal strips around each tooth. The strip would then be connected to a wire to apply force for teeth straightening. In 1970's dental adhesives were introduced which stuck braces directly to the teeth. In addition to the dental adhesive, tie wires and elastic ligatures were often used to keep the braces tight and in place. Holding the archwire to the bracket was quite time consuming and this lead to the development of self-ligating brackets. Self-ligating brackets have an additional advantage of reducing force acting on the teeth and thus are more comfortable to the patients.

In orthodontic treatment pressure is applied to the teeth through an archwire which is inserted onto the slot of a bracket bonded to enamel, which is the outermost layer of a tooth (Fig.1). Brackets are to be bonded to enamel and for that purpose is equipped with a mesh, a network of grooves which provides interlocking of metallic surface with the adhesive used to retain them onto the enamel surface.



Fig 1. Orthodontic braces with arch wires fixed on teeth

The surface of bracket which contacts the wire should be stiff to resist any deformation while the base of the bracket that contacts the enamel should be deformable to allow easy removal of brackets after completion of treatment. A wide array of methods has been used for manufacturing of Orthodontic brackets. A broad range of raw materials such as metals and alloys (austenitic and martensite stainless steels, commercially pure titanium and titanium alloys, cobalt-chromium alloys etc.), ceramic, and plastics are used. Metallic brackets which are made of stainless steel are the most commonly used in orthodontic therapy and are manufactured by three main processing methods: casting, injection molding and milling, which may be used in combination.

#### Investment casting:

#### Advantages

•The Investment Casting process has its advantages in that it is suitable to make parts with complex designs, whereas other processes are either too long and costly or there are no flash or parting lines. Otherwise, investment casting's simpler technology and dimensional accuracy is better than the other processes.

•Biggest advantage of investment casting is that it is possible to produce a very wide variety of products across different industries. This versatility is a definite plus over other casting method that either have difficulty producing some designs or cannot produce them at all. Also, many different metals and alloys can be used in investment casting.

#### Disadvantages:

•Large machinery is required for this process, and when extremely high-volume manufacturing is desired, the associated costs and longer cycle times can make investment casting a less-suitable option depending on one's needs and deadlines.

•Although investment casting saves on cost in a variety of ways, prep work can be labor-intensive compared to other methods. The preparation of the wax patterns and shell molds require much time and effort to ensure a quality product.

The first process in investment casting is producing the wax pattern of an orthodontic bracket. Injection machines are used that inject the wax into the mold. Then, the wax pattern of the orthodontic bracket assembly is shaped into the tree form. The next step is to build a ceramic shell around the wax tree. This shell will eventually become the mold that the metal is poured in. The tree form is then dipped into ceramic slurry and allowed to harden (Fig 2.). After the ceramic slurry hardens, the ceramic slurry has a thickness in the region of 10 mm. The ceramic mold is



## **Tech Speak**

then fired at a temperature over 1100°C to remove the remaining wax and to strengthen the ceramic mold. Before the metal is poured into the ceramic mold or "shell", the mold is preheated to a specific temperature to prevent the molten alloy from solidifying or "freezing off" before the entire mold is filled. Then the molten metal is poured at a temperature of over 1600°C into the ceramic mold. The next step is the cooling process. The natural cooling process is carried out at temperature of 25°C, after which the ceramic mold is broken away. Ceramic mold removal can also be accomplished chemically, using a heated caustic solution of either potassium hydroxide or sodium hydroxide, but this approach is being phased out due to environmental and health concerns. Then, the orthodontic bracket is cut from the tree form. A chemical cleaning process removes the remaining ceramic slurry, using a HF Chemical solution, followed by an ultrasonic cleaning process to achieve the final smooth casting result. The last stage is the geometric and surface roughness analysis, conducted by using a digital microscope.



#### Metal injection molding (MIM)

In this process, metal powders with particle sizes of a few microns are mixed with organic binders (typically, wax, thermoplastic resins, and other materials), lubricants until a homogeneous mixture is obtained. Injection of the feedstock is done using an injection molding machine similar to those used in the plastics industry. The injected parts, called "green parts," are formed into the desired geometry but at 17–22% oversize to compensate shrinkage after sintering. The next procedure is the "debinding," which is used to remove at least 90% of the organic binder from green parts by heat, solvent, or both (Fig. 3). The green parts have now been

transformed into "brown parts," preserving the same size with a quite porous structure. The final stage of the MIM process is sintering, which is performed in a high-temperature furnace under vacuum or a controlled atmosphere. In this stage the residual binder is removed, and at the end of the process the parts have shrunk by 17–22%, reaching the precise desired dimensions. In certain cases, thermal or surface treatments are also required.



After the sintered bracket is obtained mesh pad is added to the base of bracket. Mesh pad are made of laminating stainless steel wires of different diameter and configuration. The size of the wire mesh used in manufacturing of various single mesh type bases are 40, 60, 80 and 100 meshes. The finest mesh that can be used on metal bracket is 100 gauge, which can accommodate up to 155-micron particle size of filler present in the orthodontic adhesive. Spot welding and brazing are the methods by which mesh can be attached to the bracket base.

In spot welding the strands within the mesh are welded to each other and to the base of the bracket. Spot welding process damage the mesh base by creating flat areas where the welds occurred. These flat areas create voids in the base adhesive interface that are potential areas where brackets can detach. Additionally, the spot-welded areas create metal spurs that prevent complete seating of the bracket. It also creates an area of stress concentration by decreasing the area available for retention which may initiate fracture of the adhesive at adhesive-bracket base interface. These shortcomings are overcome when mesh base is united with brackets via brazing instead of spot welding.

Brazing: Brazing is a process where metal parts are joined together by melting a filler metal between them at a temperature below the solidus temperature of the metal being joined and the melting point of the filler is above 840 degree F. Brazing of the mesh strands instead of spot welding does not flatten the wires. The brazing layer contains a combination of silver, gold or



## Tech Speak

Thus, an attempt is made to maximize the area for interlocking potential by making more space for bonding agent. Brazing alloy is used to join wing and the base and mesh to the base. Brazing filler alloy is applied in between the bracket base and the wing interface. Most stainless-steel alloys can be brazed with any one of several different filler metal families, including Ag, Ni, Cu and Au. Initially, stainless steel brackets were brazed using silver based filler alloys which is the most frequently used brazing filler. Cadmium was added to lower the melting temperature and improve wetting. Silver based brazing alloy introduces a galvanic corrosion with release of metallic ions with Copper and Zinc the most easily leached out element from the silver brazing alloys. This galvanic corrosion is the main reason for progressive dissolution of the brazing filler metal leading to detachment of wing from the bracket base during treatment. To overcome this problem gold based brazing materials have been developed. However, this may lead to dissolution of stainless steel, which is less noble than the gold alloys and may be the reason for in-vivo corrosion of bracket bases as well as for Nickel leaching from stainless steel alloys. When gold based brazing alloy are used there is minimal alloying with stainless steel base metal therefore exhibiting good ductility, strength and corrosion resistance. Brackets travel through a brazing furnace to complete the process.

Brackets go through a final finishing step giving them a smooth polished finish

Color-coding is applied prior to final inspection. All brackets are inspected for quality assurance throughout the manufacturing process and prior to packaging.

The advantages of MIM includes:

•Very complex-shaped parts can be manufactured with or without very little secondary finishing. Undercuts in the parts, which are not possible with conventional sintering processes, can be realized with the MIM Process without problems.

•The surface of MIM parts is far superior to that of precision cast parts. Thereby, finishing and polishing costs can be eliminated or substantially reduced.

•The MIM process reaches densities of between 96% and 100% of the theoretical material density

•The MIM process allows an accuracy of better than +/-0.3% of the required dimensions.

The disadvantages of MIM are:

· High initial tooling and machinery cost.

- · Part design restrictions.
- Small runs of parts can be costly

MIM is the least expensive mainly due to material savings during the production cycle because runners and sprues can be easily recycled and reused. Casting is the most expensive because it is estimated that 90% of the metal used is wasted in sprues and runners. MIM allows the use of any alloy for the production of orthodontic brackets, which is not always the case with the other processes. As single-piece appliances, MIM brackets are expected to be free of the corrosion consequences associated with the galvanic couple of brazing alloys with stainless steel (SS).

#### One-piece brackets

The brackets are usually manufactured in two pieces i.e. bracket top portion is fabricated separately either by casting or MIM technique, the mesh is attached latter with brazing as discussed. However to cut down on the cost and reduce the number of steps in production, a few companies fabricate one piece brackets, where instead of separate mesh, indentations are incorporated in the bracket design itself. The brackets made as one piece are very rigid as there is no flexibility between mesh and the bracket top. Therefore during removal of the brackets the bond between rigid bracket base and adhesive does not break leading to fracture of enamel leading to permanent damage to the tooth surface.

The biocompatibility concerns deriving from the application of Nickel containing alloys in the oral cavity of humans for extended periods of time have provoked the fabrication of alternative materials. Thus, non-metallic, nickel-free alloys or steels with reduced nickel content have been tried in orthodontics. Titanium (Ti) has been recently introduced as an alternative material in the production of metallic orthodontic brackets. The reason underlying the choice of this metal resides in its proven biocompatibility, lack of allergenicity and increased corrosion resistance. Laser welding is also being used. The main advantage of this method is that two alloys with different stiffness can be used, the absence of an intermediate phase and potential corrosion risk optimize the prospective performance of final products.

Dr. Sohinderjit Singh :Prof & Head Dept. of Orthodontics & Dentofacial Orthopedics Himachal Institute of Dental Sciences Paonta Sahib H.P.

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## **Member Commendation**

#### MR. PRATAP ASHER

Partner Jaypee General Agencies, Calicut, Kerala

He is one of pioneer dental traders from Kerala having started business in the year 1962. In the last 56 years of business he has literally grown with dental profession. The entire dental profession knows him as JAYPEE and his friends call him Asher. He is a person with multifarious business activities. He strongly believes in innovation for import substitution. He introduced the "Jaypee "brand of ortho pliers, which changed the way Orthodontics was learnt in India because the entire Orthodontic student community switched to the affordable "Jaypee" pliers. Unlike the previous generation which entirely depended on imported pliers.

Then again he was the first to bring out India's own Latex Elastics under brand name "HP". His elastics become so popular that today hardly anybody imports latex elastics.

He believes in the motto: "Applying innovations", and tru to his motto he has introduced new import substitute products into the Indian dental market, viz. Preformed bands, Laser welded face bows, Orthodontic arch wires and Preadjusted edgewise appliance brackets.

An active member of ADITI since its inception, hHe has held the post of South zone Secretary and President, as member of Central Executive two terms and also was member of the panel for ADITI constitution amendment and disputes conciliation committee. In addition to ADITI he is an active member of Malabar Chamber of Commerce since last 25 years and the All Kerala Chemists and Surgical Dealers Association. A founder member of Kerala Dental Dealers Association (KEDDA), he remains as Advisor of KEDDA Trade Fair since FOUR years

He was extremely involved in association activities of Kozhikode District Cement Dealers Association having held the office of Secretary for one term and also President for six years until 2001. He was honored by Sri. Nani Palkiwala, in 1996, then Chairman of Associated Cement Cos.for his meritorious service of 25 years as ACC stockist.

He has made active contribution in the field of

education. He has been on the board of Management of Sri. Gujarati Vidhyalaya Association for 32 years. He is the Past President of the association. An active member of Rotary Club of Calicut East since 1976, he has held several posts in Rotary. Past Secretary, Past President, three terms as Treasurer, three terms as Youth Service Chairman and GGR (District Governor's Group Representative).

He is also the Past President of Calicut Bhatia Mahajan, a registered society doing community service and the Dakshin Bharat Bhatia Mitra Mandal, an NGO.

Asher is known for the in depth knowledge of the products he sells and is capable of repairing most of the dental equipments. In the years, Asher has established a reputation for straight forwardness with keen business acumen.









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