

New biomaterial utilizing cellulose fibers with  
Polyamide and Polyolefin blends (PAPC) for use in  
Micro Molding

**FibreTuff Medical Biopolymers, LLC**

A Better, Natural, Cost Effective Material Solution for the Medical Market

Presentation by Robert Joyce Founder and President on August 3, 2017

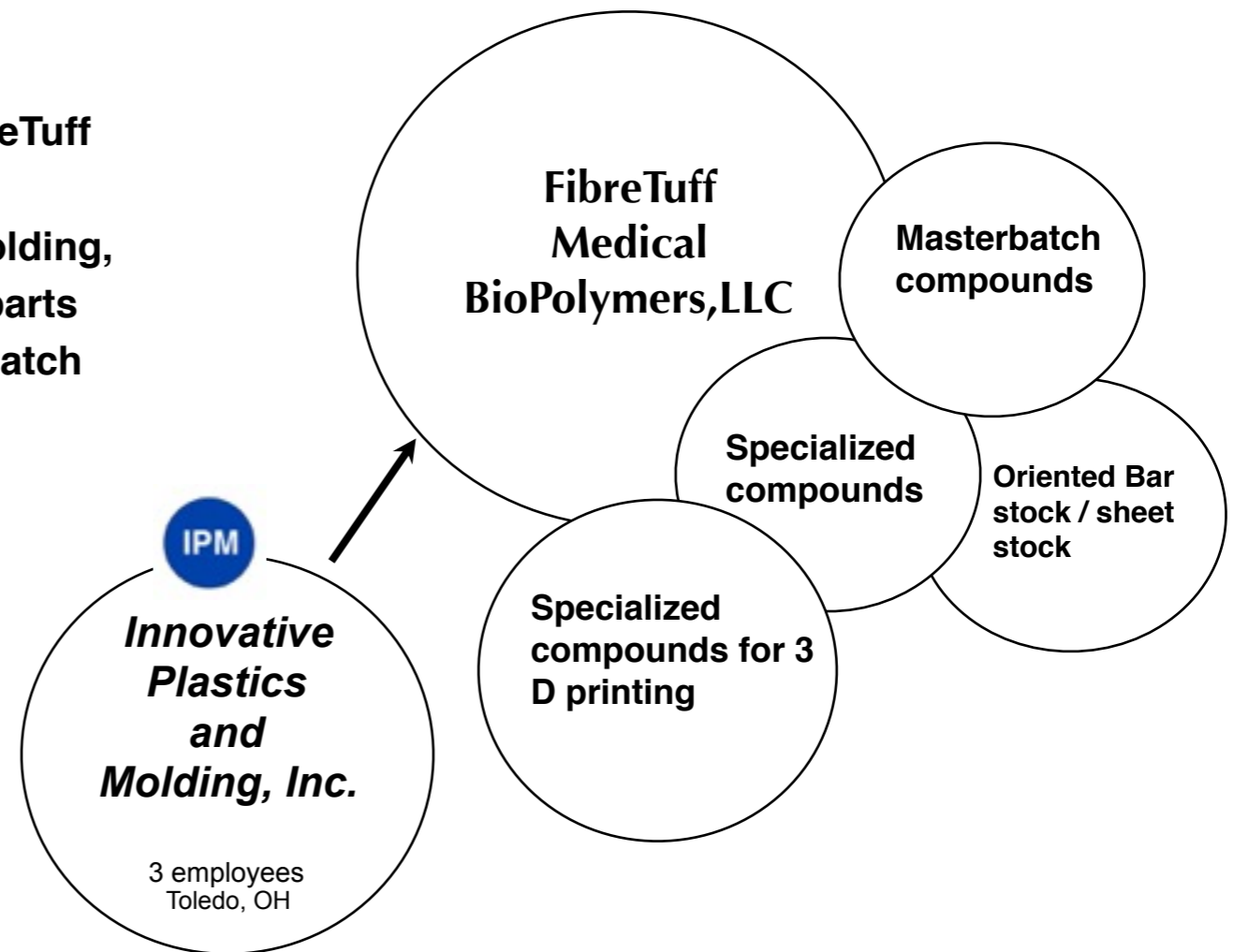
# Presentation Outline

- 1. *FibreTuff*® the company and cellulose thermoplastic technology.**
- 2. Micro Molding and Biomaterials market.**
- 3. Micro Molding and Biocompatible definitions.**
- 4. Associated challenges to micro mold biomaterials.**
- 5. Polyolefin with polyamide and cellulose fiber blends ( PAPC )**
- 6. Biomaterials chart to include Polyolefin with polyamide and cellulose fiber blends ( PAPC )**
- 7. Sodick micro molding processing**
- 8. Isometric**
- 9. Appendix: Medical applications for PAPC/ Testing / Sterilization / 3D printing**
- 10. Conclusion**

# FibreTuff Medical Biopolymers, LLC

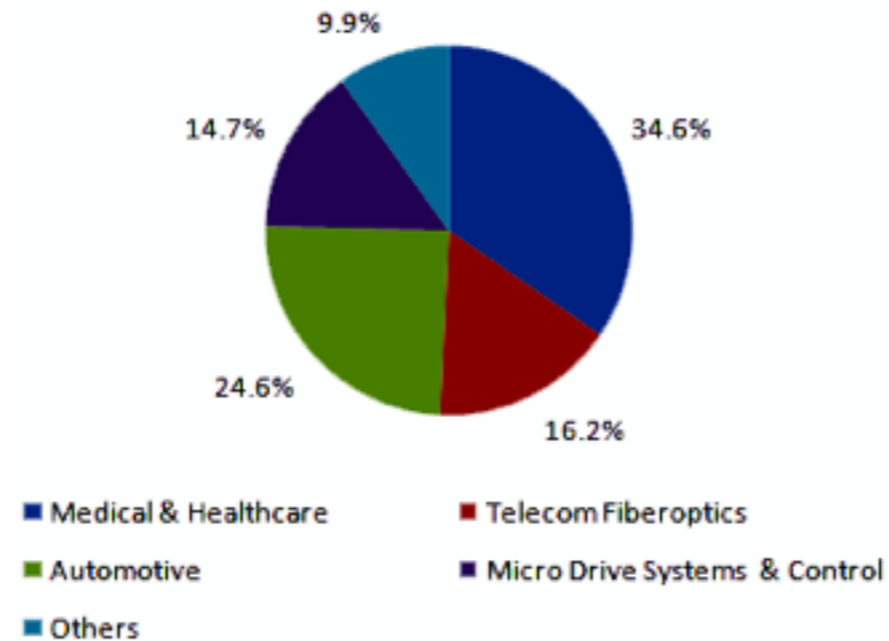
Producer of compounds utilizing cellulose with Polyamide and Polyolefin blends (PAPC) for the medical industry

A partnership that has an exclusive license on FibreTuff technology for the medical market. *FibreTuff*® technology is owned by Innovative Plastics and Molding, Inc.. The licensed technology will include molded parts and composition of matter - specialty and master batch compounds with the FibreTuff trademark. Primary customers for *FibreTuff*® biopolymers will include companies who manufacture products for into the medical device, instrument, implants, packaging companies and compounders.



# Micro Molding with Biomaterials

Applications for micro molding are industry specific with specific material requirements



**Global market for micro molding is US\$897 million by 2020**

- North America has been leading the polymer micro molding market and is expected to grow at a CAGR of approximately 14.5% between 2013 and 2019.
- Europe emerged as second largest polymer micro molding market and is expected to account for nearly 36% of the total market in 2019.
- Asia Pacific is expected to grow at an estimated CAGR of 14.6% from 2013 to 2019.

\*Implantable biomaterials Markets Analysis and Trends -material, application forecast to 2025 and Transparency Market Research

# Micro molding and Biocompatibility definitions

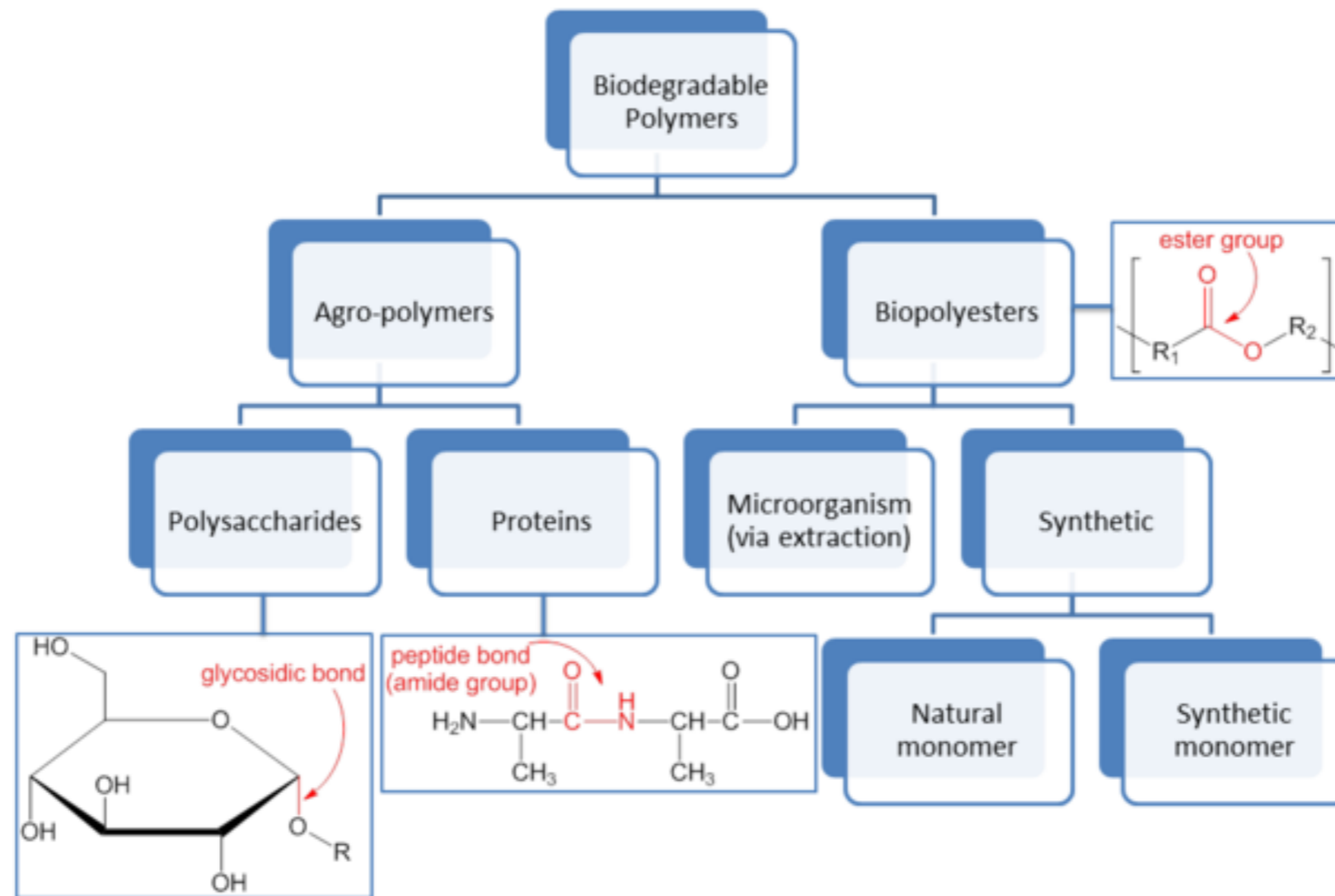
**Micro molding** is a injection molding process which requires a specific molding machine with high injection pressure and speed, precise shot control, and ultra fine resolution for molding small sized tools and parts. Micro injection molding is usually done for the parts that are designed with weight less than a milligram and size less than 1mm

**Biomaterial** is any substance that has been engineered to interact with biological systems for a medical purpose - either a therapeutic (treat, augment, repair or replace a tissue function of the body) or a diagnostic one

**Biocompatibility** The ambiguity of the term reflects the ongoing development of insights into the interaction with the human body and eventually how those interactions determine the clinical success of a medical device (such as pacemaker, hip replacement or stent). Modern medical devices and prostheses are often made of more than one material so it might not always be sufficient to talk about the biocompatibility of a specific material.

**Bio absorbable** capable of being absorbed into living tissue.

**Bio re sorbable** (called biodegradable, or naturally-dissolving) is manufactured from a material that may dissolve or be absorbed in the body.



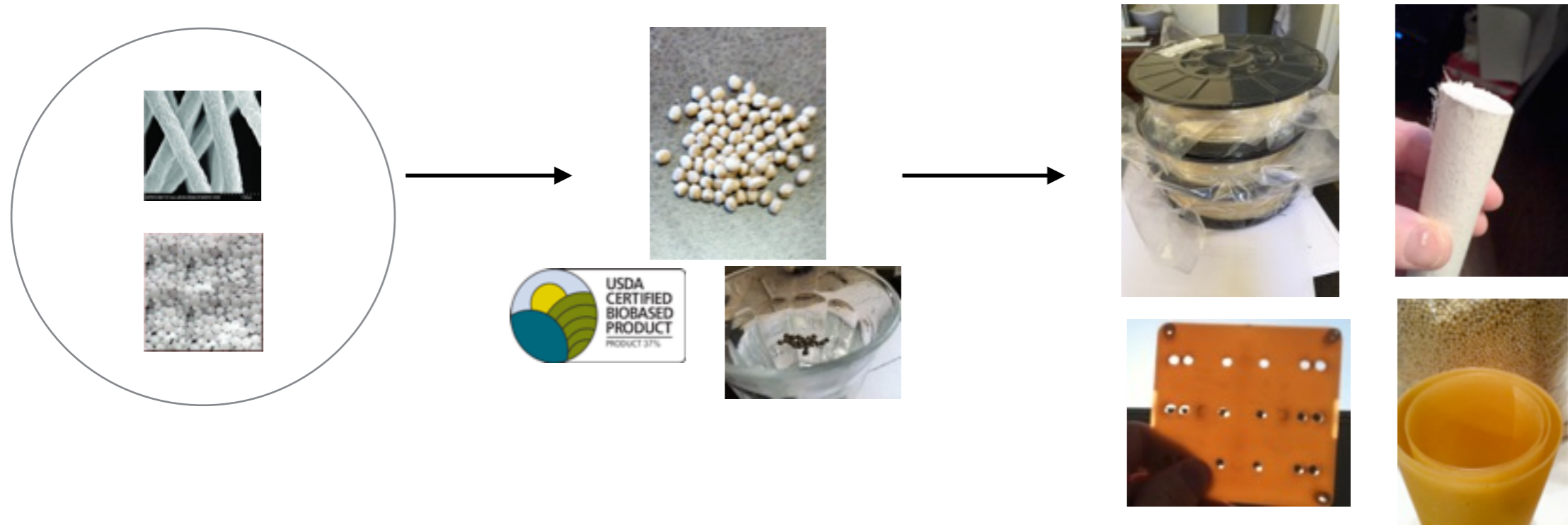
- **Agro-polymers include polysaccharides, like starches found in potatoes or wood and proteins, such as animal based whey or plant derived gluten.**
- **Cellulose is an example of a structural polysaccharides.**
- **Proteins are made from amino acids, which contain various functional groups. These amino acids come together again through condensation reactions to form peptide bonds, which consist of amide functional groups.**

# Associated Micro Molding challenges with Biomaterials

- Drying and post processing can be extensive task. Expensive
  - Biomaterials are very hydrophilic and require special packaging for compounders and molder. Hygroscopic
  - Requiring 8 to 10 hrs of desiccant drying time. High moisture content
  - Ability to grow mold and fungus - anti microbial.
  - Very Heat and shear sensitive. Odor
- Utilizing Standard Sterilization methods.
- Gate locations need to be optimized.
- Zero flash isn't required and a deterrent to mold a successful part.
- Sustaining extremely tight tolerances on long runs must be avoided.
- Shear and heat sensitive. Processing sensitivity
- Processing a bio fiber with FDA compliance and biocompatibility.

# Polyamide with Polyolefin and cellulose fiber blends(PAPC)

Bio absorbable, not re sorbable, biocompatible, contains polysaccharides, proteins, peptides with hydrophilic and hydrophobic effects .....



- Cellulose is biodegradable by nature but not in the human body “The body likes cellulose”
- Hydrophobic interaction interaction is the foundation for the existence of life.
- Hydrophilic interaction i.e. Polyamides include proteins and peptides which are naturally produced polymers consisting of amino acid repeating units.





# Characteristics of the Biomaterial PAPC

- No offensive odor
- Transparency
- Biocompatible
- FDA compliant ingredients.
- Isotropic and good elastic qualities
  - Mold Shrinkage Report method used, sample size and value) After 48 h at 23+/- 2 °C Flow (F), Cross Flow(CF) F .90% CF .99%
  - Elongation at Yield ISO 527-1 & ISO 527-2 50mm/min 5.3 %
- Good thermal stability.
  - Wide processing window 193C - 226C
  - HDT ISO 75-1 flatwise, 264psi 86 C
  - Cellulose fiber has a TG 230 - 250C.
- Chemical resistance - good, required in some applications.
- Compressibility.
- Adhesion properties.

# **Creating new micro molding devices with PAPC and lowering costs**

## **Replacing existing biomaterials**

- **Devices needing bio absorbable qualities.**
- **Not re sorbable in the human body.**
- **Devices requiring Standard Sterilization methods.**
- **Sensitive tooling constraints - long production runs.**

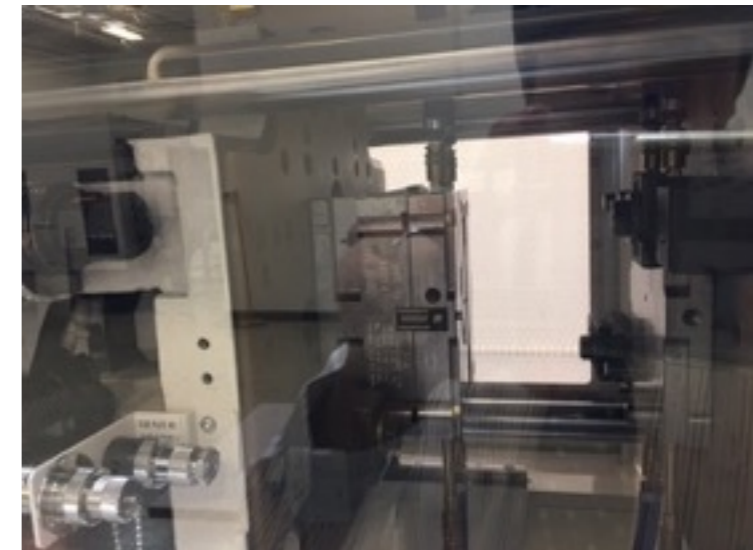
## **Cost Benefits**

- **Specific Gravity is 20 to 30% less**
- **Doesn't require specialized packaging.**
- **Not very hygroscopic at 10-30% cellulose**
- **No Extensive drying - at 20% cellulose with high heat polymer .21% Test method ISO 62 24 hr. immersion.**

# Process validation of PAPC

- Sodick injection system is good for FiberTuff material evaluation per Kohei Shinohara.
- Sodick utilizes a proprietary two-stage V-LINE method for plasticizing and injection functions.
- Both 14mm screw and 18mm screw were used to mold. The feeding is better on the 18mm screw but both small screw treat the raw material of FiberTuff biopolymers.
- The process was very stable and the parameters were consistent.

**Sodick**



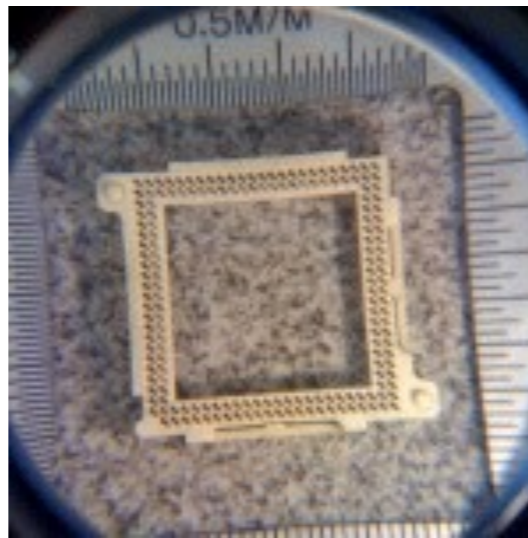
**Sodick injection system**

# Micro Molder evaluation of PAPC

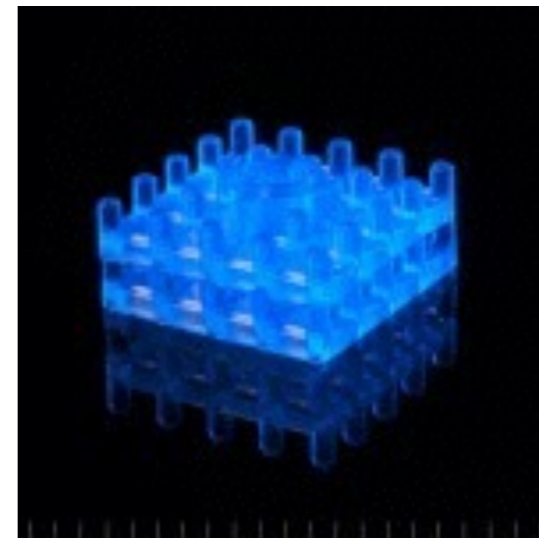
- Filled product as small as 0.003”
- Bio absorbable is good for drug delivery and adhesion for coatings.
- Not shear sensitive



The tip of these micro molded needle arrays are very sharp. There's a .002” (50 micron) hole in each one and they are .100” high



A LCP micro molded electronic micro connector with 0.0002” (5 micron) molded pin receivers and showing low shrink



A micro molded facial reconstruction device made from bio-resorbable polymer and featuring a 0.003” (75 micron) ultrasonic weld bead



# Cont'd: Micro Molder evaluation of PAPC

## Moldability Results

	Parameters	Result	Comment
1	Drying	Good	no issues drying/maintaining material
2	Feed to Screw	Good	
3	Metering	Good	
4	Thermal Stability/Interrupt Tolerance	Variable	material degradation issues
5	Flow	Good	
6	Flash	Good	
7	Demold	Good	

## Notes:

Material degrades when sitting (no movement) in barrel at processing temps for extended periods of time lasting longer than 30 minutes. Degraded material can be purged through to "clean" material without issue. Material flows well and fills thickness plaque 0.007" under all injection rates. Cannot fill less than 0.004" thickness plaque under fastest injection rates. Cellulose filler seemed to have little affect on inhibiting polymer flow.

## Suggestions:

Post molded product should be evaluated for Cellulose content via FTIR, DSC, or Mass Spectroscopy.

# PAPC and Class I testing

## Passed Skin Irritation and Cytotoxicity testing

- **Skin Irritation results:**

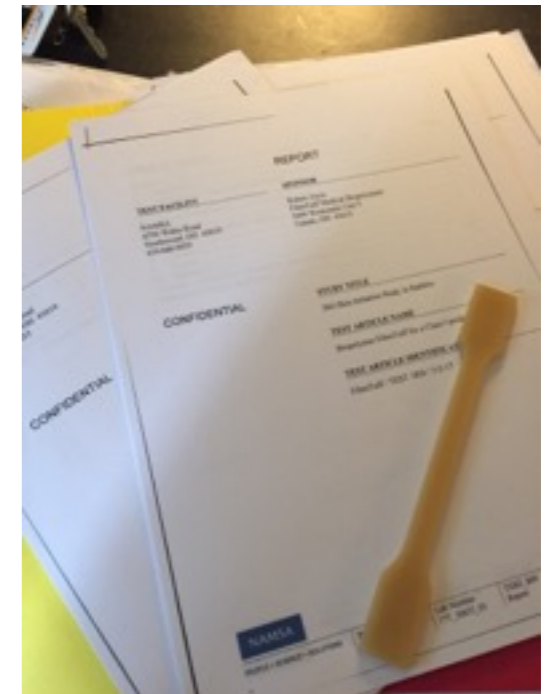
The test article, Biopolymer FibreTuff for a Class I product, was evaluated for primary skin irritation in rabbits. This study was conducted in accordance with the guidelines of ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for a minimum of 23 hours and a maximum of 24 hours.

The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

- **Cytotoxicity results showed the following results:**

The test article, Biopolymer Fibre Tuff for a Class I product, was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

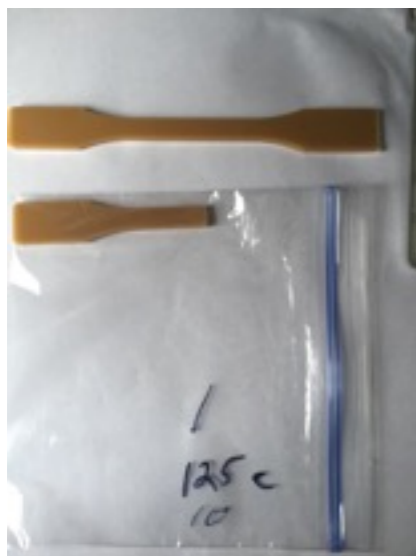
The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than or equal to a grade 2 (mild reactivity).



NAMSA Reports

# PAPC utilizes existing sterilization techniques

- Improved Biocompatibility with hydrophilic and hydrophobic resins and cellulose.
- Sterilization testing in Autoclave and Gamma
- High heat polymers such as Polyamide



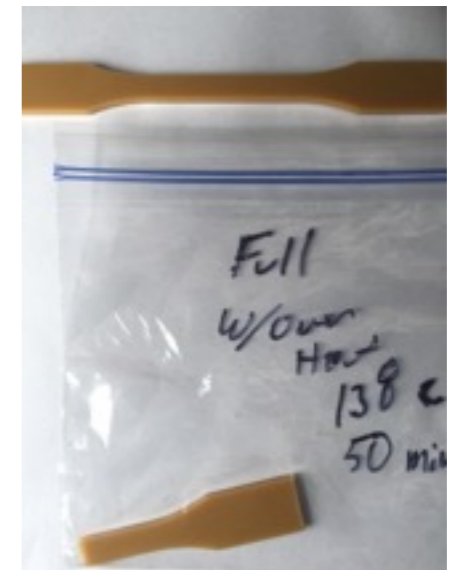
257 F / 125 C exposure @ 10 min. applied bacterial contamination before Autoclave and tested.



280 F / 138 C exposure @ 10 min.



280 F / 138 C exposure @ 30 min.



280 F / 138 C exposure @ 50 min.



# Appendix: Medical Applications for PAPC

Medical applications include products that can require the following qualities: absorbable, non re sorbable, good compressive strength, in growth, elastic, lightweight, lower cost qualities, anti mold.

- Focus on replacing styrene ABS, PP and PEEK for class I, II and III devices.
- Process applications include injection molding, sheet and profile extrusion, 3 D printing.

## Class I devices

Tongue depressors  
Bandages  
Gloves  
Bedpans  
Simple surgical devices



Medical Tray

## Class II devices

Wheelchairs  
X-ray machines  
MRI machines  
Surgical needles  
Catheters  
Diagnostic equipment



Orthotics

# Appendix: PAPC Molding Conditions and Specification

## Optimized conditions for molding PAPC

**Desiccant dryer for 2.5 hrs min. at 180 F.**

**Moderate to high back pressure.**

**4-6" injection speed.**

**Tool temperature at 100F to 120 F.**

TEST	ISO	UNITS	RESULTS
Tensile Str. @ Yield	ISO 527	Mpa	41
Tens. Elong. @ Yield	ISO 527	%	3.2
Flexural Strength	ISO 178	Mpa	60
Flexural Modulus	ISO 178	Mpa	2,540
Izod Impact Strength	ISO 180	kJ/m2	3.69
Specific Gravity	ISO 1183		1.0190
Gardner Impact	D5420	ft.lbs.	
Heat Deflection	ISO 75	°C	85.70
Color		Visual	
Flame			
Flow Rate *	D1238	gr / 10 minutes	5.7
Ash *	D5630	%	
Moisture	D6980	%	0.07

# MIT demonstrates 3D printing with cellulose, as an alternative to petroleum based plastics

07 Mar 2017 , 15:35

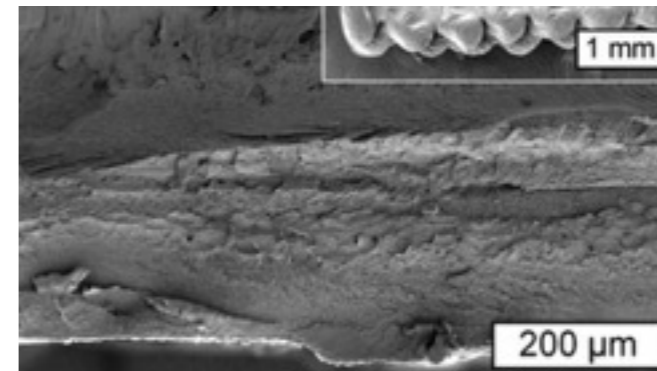
#MIT

*3D printed structure and closeup. Image: MIT.*

Plants could be a renewable and biodegradable alternative to the polymers currently used in 3-D printing materials, researchers have found. A new paper, published in the journal *Advanced Materials Technologies*, found that cellulose might become an abundant material to print with. “Cellulose is the most important component in giving wood its mechanical properties. And because it is so inexpensive, it is biorenewable, biodegradable and also very chemically versatile, it is used in a lot of products,” said Sebastian Pattinson, lead author of a paper, from Massachusetts Institute Of Technology (MIT). “Cellulose and its derivatives are used in pharmaceuticals, medical devices, as food additives, building materials, clothing — all sorts of different areas. And a lot of these kinds of products would benefit from the kind of customisation that additive manufacturing [3-D printing] enables,” Pattinson added. When heated, cellulose thermally decomposes before it becomes flowable, partly because of the hydrogen bonds that exist between the cellulose molecules. The intermolecular bonding also makes high-concentration cellulose solutions too viscous to easily extrude.



*A pair of tweezers made using cellulose. An anti-bacterial die was used to make the instrument safe for use for medical purposes.*



*3D printed structure and closeup. Image: MIT.*

# PAPC a new biomaterial for micro molding



**Advanced biomaterial composition PAPC will grow to fill a void in the micro molding market to help provide lower costs and improved performance characteristics.**

Using biological materials may not only be better for the environment, but better for the human body.

# Thank You

FibreTuff® biopolymers is now a proven biopolymer material science technology with an excellent value proposition for the medical market.

**More information**      **[www.FibreTuff.us](http://www.FibreTuff.us)**