

Plastics for Medical Devices

April 20, 2010

Trends for Plastics in Medical Devices

Len Czuba

Czuba Enterprises, Inc.

www.czubaenterprises.com

Overview

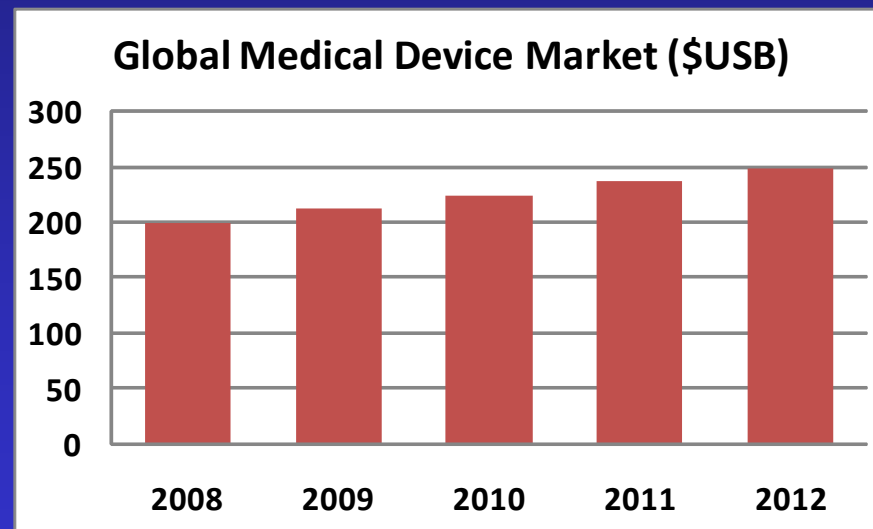
1. The medical device industry
2. Healthcare trends
3. Device materials in common use
4. Trends leading to new material requirements
5. Market factors affecting the industry
6. Several case studies

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1. The Medical Device Industry

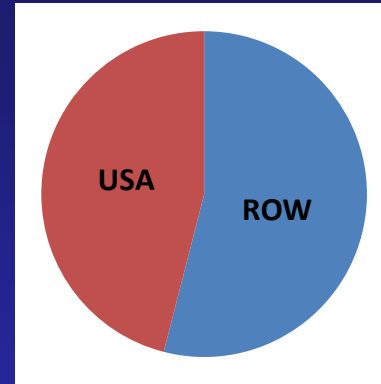
- Total size
- Growth trends



Internet source: www.devicelink.com/mddi/archive/09/07/010.html

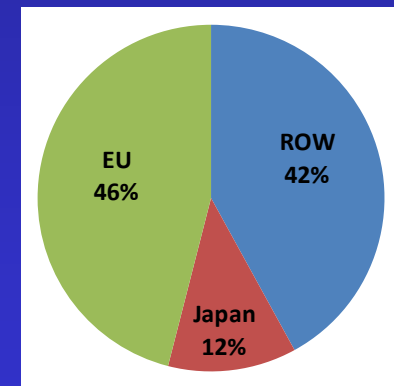
1. The Medical Device Industry

- Total size
 - about \$200B
 - est. to be \$250B by 2012



<http://www.devicelink.com/mddi/archive/09/07/010.html>

- US consumes 45-47% of world market
- US exports (\$37B) distributed to
 - EU 46%
 - Japan 12%
- Rest of World: growing rapidly



1. The Medical Device Industry

- Growth trends in
 - Brazil, Russia, India, and China (BRIC)
 - Africa
 - Middle East
 - Eastern Europe
- Needed: healthcare delivery infrastructure
- Needed: stable political environments

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2. Healthcare Trends

- Minimally invasive surgeries
- Alternative site treatments
- Prevention vs. Treatment

2. Healthcare Trends

- Minimally invasive surgeries
 - SILS Port, **Multiple Instrument Access Port**

COVIDIEN



Internet source: www.covidien.com/campaigns/pagebuilder.aspx?topicID=175991&page=SILSPort:Main

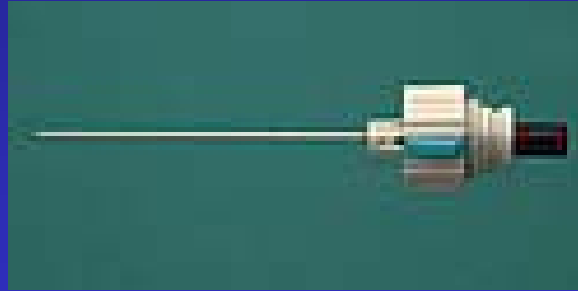
2. Healthcare Trends

- Minimally invasive surgeries
 - SurgiSil port, **Multiple Instrument Access Port**



2. Healthcare Trends

- Minimally invasive surgeries
 - Microendoscopes less than 1.5 mm diameter
BIOVISION TECHNOLOGIES



Internet source: <http://www.devicelink.com/mddi/archive/09/07/011.html>

2. Healthcare Trends

- Minimally invasive surgeries

- Novare Surgical Systems:

- RealHand
High Dexterity
Instruments



Internet source: www.novaresurgical.com/realhand-hd-instruments/realhand-products/

2. Healthcare Trends

- Alternative site treatments

for entire spectrum of services such as:

- Surgery to Chemotherapy
- Hemodialysis to Physical Therapy
- Elderly care to Rehab Services

2. Healthcare Trends

- Prevention vs. Treatment

via:

- Improved diagnostics
- Genetic testing
- More frequent or even constant monitoring
- Earlier onset of treatment

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3. Device Materials in Common Use

- Thermoplastics
- Thermosets
- Silicones
- LSRs
- TPEs
- Biomaterials
- Biomaterial products

3. Device Materials in Common Use

- Thermoplastics
 - Commodity
 - Engineering
- Thermosets
 - Urethanes
 - Epoxies
 - UV cured
 - TPV



Internet source:
www.solvayadvancedpolymers.com/services/photogallery/0,,10509-2-0,00.htm



Specialty thermoplastics
Solviva family of biomaterials
for use in implantable medical
devices by SOLVAY.

Internet source: www.solvayadvancedpolymers.com/services/photogallery/0,,10509-2-0,00.htm

3. Device Materials in Common Use

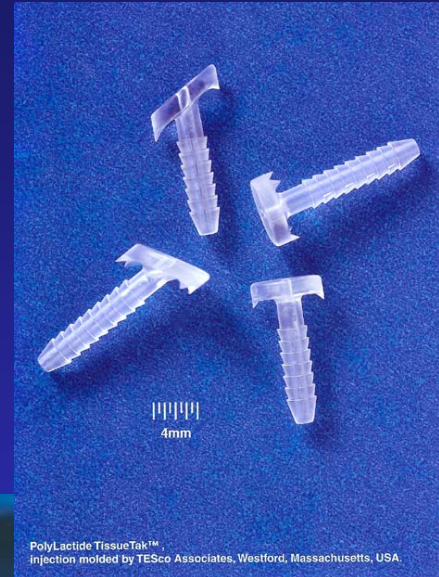
- Silicones
 - NuSil
 - Dow Corning
 - Wacker
- LSRs
- TPEs
 - GLS & Kraton
 - Krieberg



ARBURG Internet source:
www.arburg.com/com/common/press/picture/14556-01-Spritzlinge_LSR.jpg

3. Device Materials in Common Use

- Biomaterials
 - PLA / PGA / PGLA
 - PURAC
 - PEEK
 - Invibio and Solvay



Invibio: Spinal Cages



Invibio: Ligament Fixation Washers

Internet source: www.invibio.com/biocompatible-polymers/biocompatible-polymers.php

3. Device Materials in Common Use

- Biomaterial products
 - Bone grafts and scaffolding
 - Anti-adhesion sheeting, spray, gel
 - Tissue scaffolding



Internet source:
www.puracbiomaterials.com/purac_bio_com/234fbe78dc9d1b206d0c135a67d76e38.php

Overview

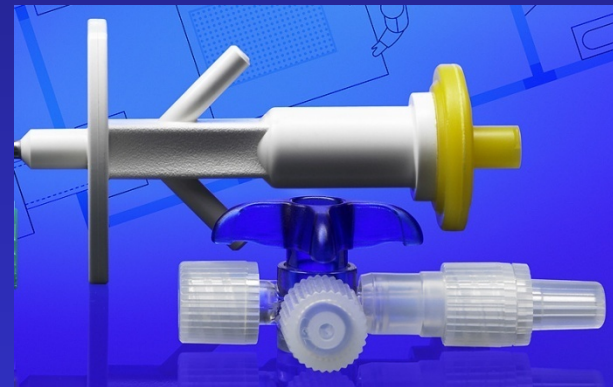
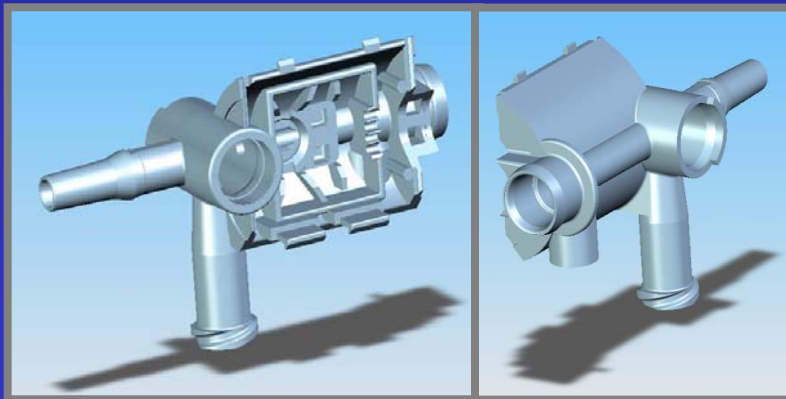
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4. Trends Leading to New Material Requirements

- Functionality
 - Compatibility
 - Cost – always an issue
 - Device & Process Technology Innovations
 - Ecological / Environmental Concerns
 - Influence of consumer in decision making
-

4. Trends Leading to New Material Requirements

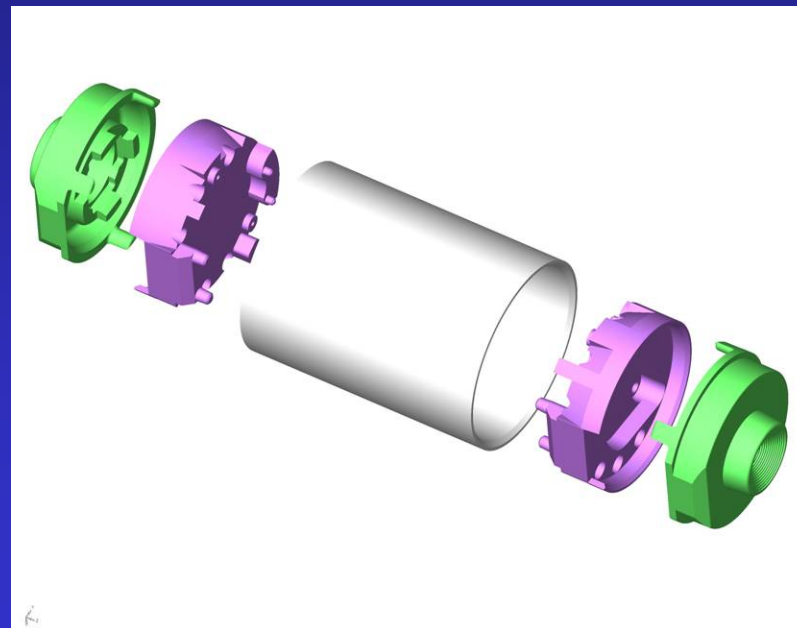
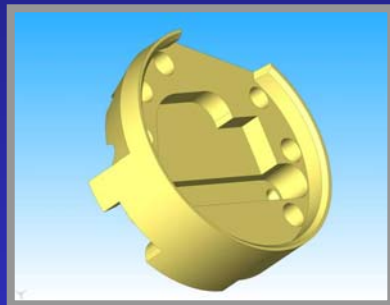
- Functionality
 - Metal replacement
 - Cost savings: consolidation of parts
 - Assembly efficiency
 - Weight savings
 - MRI compatibility



ARBURG Internet source:
www.arburg.com/com/common/press/picture/17010-01-Spritzlinge_Reinraum.jpg

4. Trends Leading to New Material Requirements

- Functionality
 - Smaller components for smaller instruments
 - Miniature and micro molding



4. Trends Leading to New Material Requirements

- Functionality
 - Device tracking – RFID and Primary polymer ID



Internet source: https://w1.siemens.com/innovation/en/publikationen/pof_fruehjahr_2009/digitale_waechter/echtheit.htm

4. Trends Leading to New Material Requirements

- Compatibility
 - Multi-material construction
 - Multi-molded / two-shot molding



Molded-in Gaskets

ARBURG Internet source: www.arburg.com/com/common/press/picture/15406-01-Spritzlinge_Spezialverfahren.jpg



Tools for Orthopedic Surgery



Silicone Catheter

4. Trends Leading to New Material Requirements

- Compatibility
 - Longer term implant
 - Reduced wear
 - Matched stiffness for bone replacement
 - Adhesion promotion



Invibio: Spinal Cages

Internet source:
www.invibio.com/biocompatible-polymers/biocompatible-polymers.php

4. Trends Leading to New Material Requirements

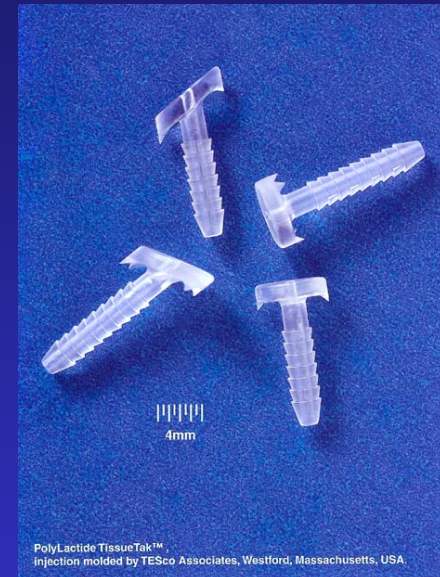
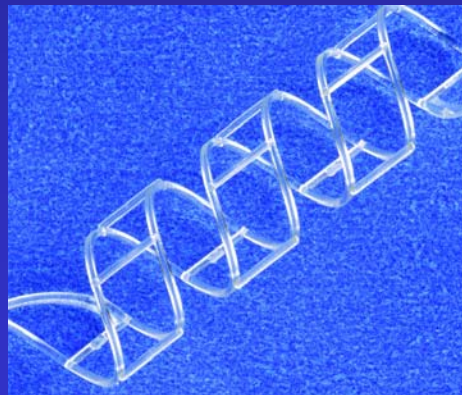
- Compatibility

- Resorbability

- Sutures
 - Tissue anchors / Bone screws
 - Reinforcement mesh and Stents



[Inion Ltd, Guildford (UK)]



PolyLactide TissuTak™
injection molded by TESco Associates, Westford, Massachusetts, USA.

4. Trends Leading to New Material Requirements

- Cost – always an issue
 - Light weighting
 - Improved designs
 - Design for Manufacturing (DFM)
 - Use of commodity materials
 - Combined use – increase volumes purchased



4. Trends Leading to New Material Requirements

- New Device & Processing Technologies

- Micro Molding

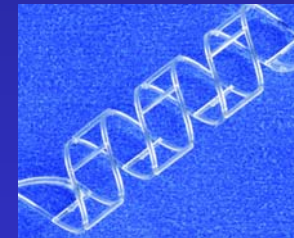


- 2-Shot and Over Molding

- Metal Injection Molding

- Insert Molding

- Combination Devices – DES, Resorbables, etc.



4. Trends Leading to New Material Requirements

- Ecological / Environmental Concerns
 - Packaging
 - Reduce waste
 - Recycle
 - Renewable resources

4. Trends Leading to New Material Requirements

- Influence of consumer in decision making
 - “Paper or Plastic” and foam vs. paperboard
 - Concentrated liquids
 - Rethinking procedures
 - Reuse / Reprocess
 - IV change frequency
 - Antimicrobial surfaces



Internet source:
www.stewartspackaging.com/index.as

Overview

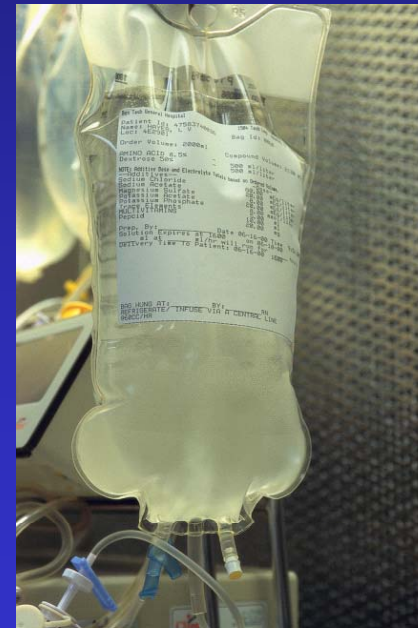
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5. Market Factors Affecting the Industry

- Phthalate plasticizer issue
- Chlorine polymers and disposal
- BPA and questions of safety
- The need for “Green”
- Globalization of markets
- Globalization of manufacturing
- Global influences

5. Market Factors Affecting the Industry

- Phthalate plasticizer issue
 - No action by FDA speaks volumes



5. Market Factors Affecting the Industry

- Chlorine polymers and disposal
 - Alternative technologies closer



5. Market Factors Affecting the Industry

- BPA and questions of safety
 - Fact or Hype?
- The need for “Green”



5. Market Factors Affecting the Industry

- Globalization of markets
- Globalization of manufacturing
 - Energy costs affects transport of products
- Global influences
 - Infectious diseases
 - MRSA, SARS, H1N1
 - Economic pressure
 - Food / Sanitation / Healthcare needs

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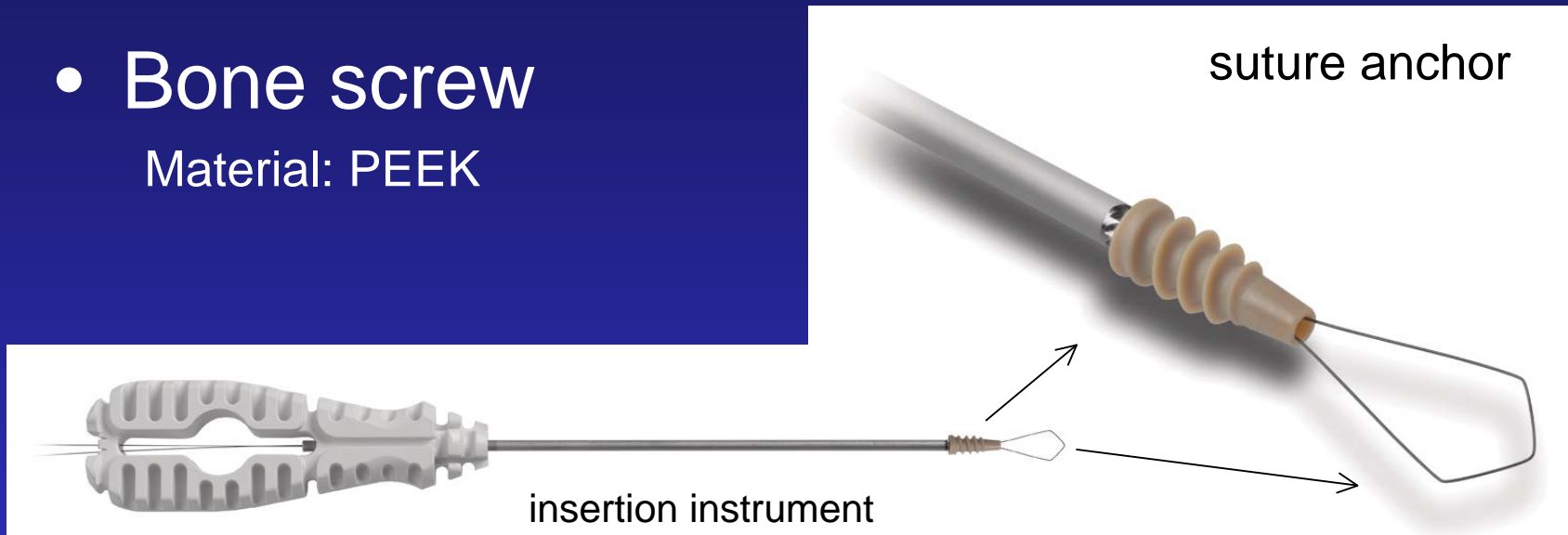
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6. Several Case Studies

- Bone screw
- AbsorbaTack
- Non-PVC containers and accessories
- Biohazard Respirator Mask

6. Several Case Studies

- Bone screw
Material: PEEK



Biomet Sports Medicine / PMC Smart Solutions (injection molding)

6. Several Case Studies

- AbsorbaTack



Len Czuba
April 2010

by Covidien

absorbable synthetic polyester copolymer derived from lactic and glycolic acid

6. Several Case Studies

- Non-PVC containers and accessories

Eastman Chemical Company

Ecdel thermoplastic elastomers and Eastar copolyester plastics.



Internet source: www.eastman.com/medical

Achilles USA

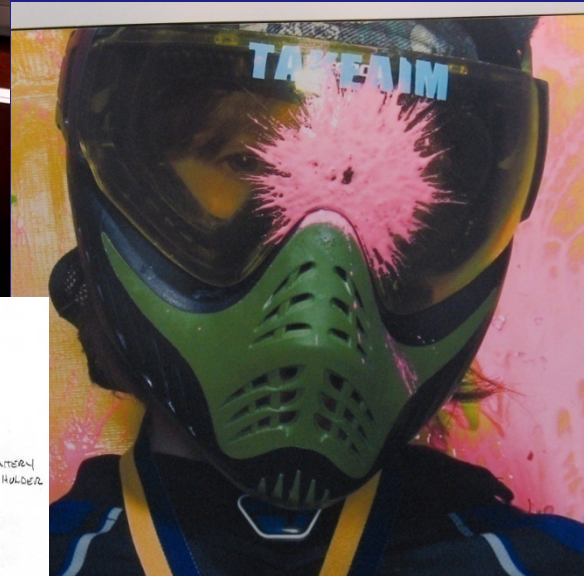
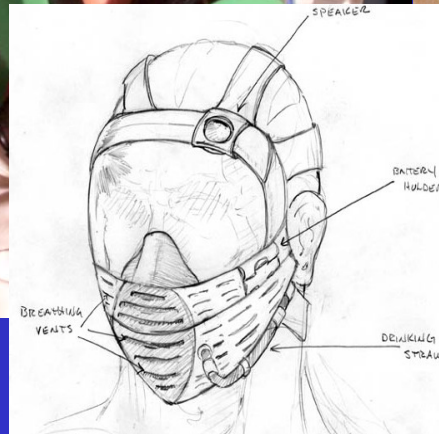
EVA and Olefin film laminates



Internet source: www.achillesusa.com/plastic-health.php

6. Several Case Studies

- Biohazard Respirator Mask

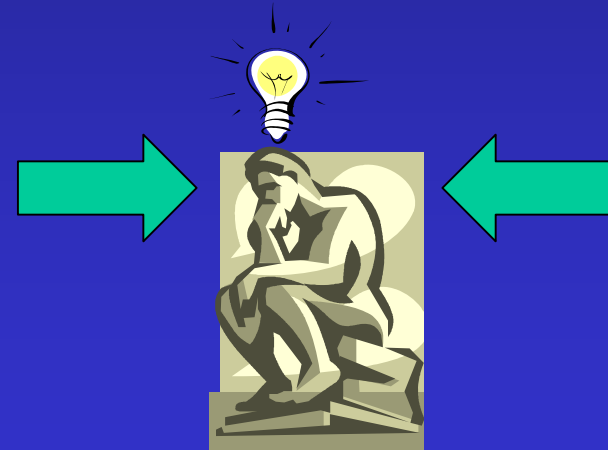


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Summary and Conclusions

- Exciting time to be in this industry
- New developments improve lives
- Innovation is usually rewarded
- Convergence benefits the open mind



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