

**NPE 2024** | **MADE FOR YOU**  
The Plastics Show

Produced by  **PLASTICS**  
INDUSTRY ASSOCIATION

May 2024

# Transforming Healthcare Delivery: ECA & Syensqo's Strategic Partnership

---





**SYENSQO**



# **1 Company Overview**

## Established Platform & Brand...

**#1**

Med-Tech Torque Limiter Worldwide

**45+**

Years Serving Medical Device Leaders

**48M+**

Torque Limiters Distributed Worldwide

**500K+**

Surgery-Ready Orthopedic Kits Distributed

**3M+**

Single Use Instruments Distributed Per Year

**143**

Registered and Granted Patents

## ...Offering a Complete End-to-End Solution...



## ...Across a Variety of Mission-Critical Product Types...

**POWER TORQUE DRIVERS**



**SINGLE-USE PROCEDURE KITS**



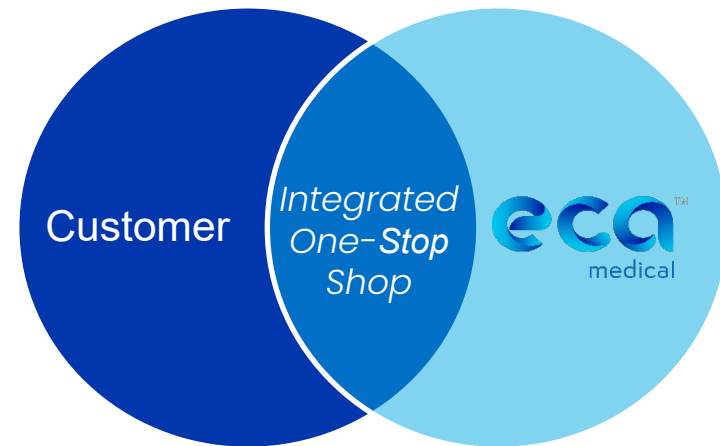
**HAND TORQUE, FIXED, & RATCHET HANDLES**



**HAND TORQUE HANDLES**



## ...Providing A Unique, Customer Solution

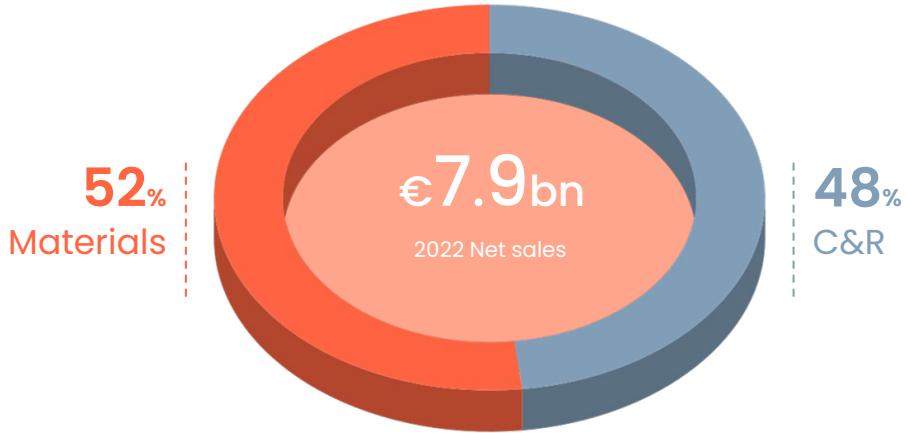


# Syensqo is a market leader in Materials & Consumers



MARKET POSITION

MATERIALS	#1	<p><b>High-performance polymers; leading position in thermoplastic composites</b></p> <p>Battery Materials, Thermoplastic composites, Green Hydrogen, Renewable materials &amp; Biotechnology</p>
	#2	<p><b>Materials for civil aerospace</b></p>
	#1	<p><b>Materials for defense</b></p>
CONSUMER & RESOURCES	#2	<p><b>Specialty surfactants and polymers</b></p>
	#1	<p><b>Flavors &amp; Fragrances; Natural Vanillin</b></p>
	#1	<p><b>Mining reagents</b></p>
	#1	<p><b>Biocides for recycled water</b></p>

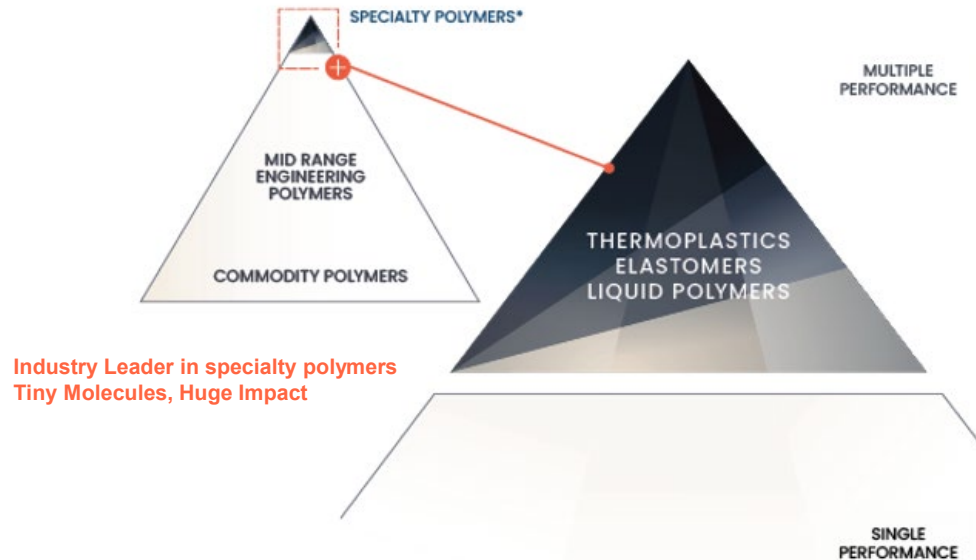


# Syensqo

We are a science company whose technologies bring benefits to many aspects of daily life.

Our innovative solutions contribute to safer, cleaner, and more sustainable products found in homes, food and consumer goods, planes, cars, batteries, smart devices, healthcare applications, water and air purification systems.

Our Group seeks to create sustainable shared value for all, crafted around three pillars: protecting the climate, preserving resources and fostering better life.



Industry Leader in specialty polymers  
Tiny Molecules, Huge Impact

**€7.9bn**

Net Sales

**€1.9bn**

Underlying EBITDA

**23.6%**

Underlying EBITDA Margin

**13,200**

Employees

**12**

Major R&I Centers

**62**

Industrial Sites

**1** In-house Sterilizers

**2** Application Development Laboratories

**3** Moldflow and FEA analysis

**4** Residual Stress testing of molded parts

**5** Chemical Compatibility testing

**6** Wide variety of molded samples available for customer testing

**7** UV, Near IR and Far IR laser marking and cutting machines

**8** In house high temperature 3D fuse filament and powder printers

# **2 Drivers & Considerations of Sterile Kits in Ortho**

# Reusable vs Single-Use

Orthopaedics is turning to Surgery-Ready™ Instruments



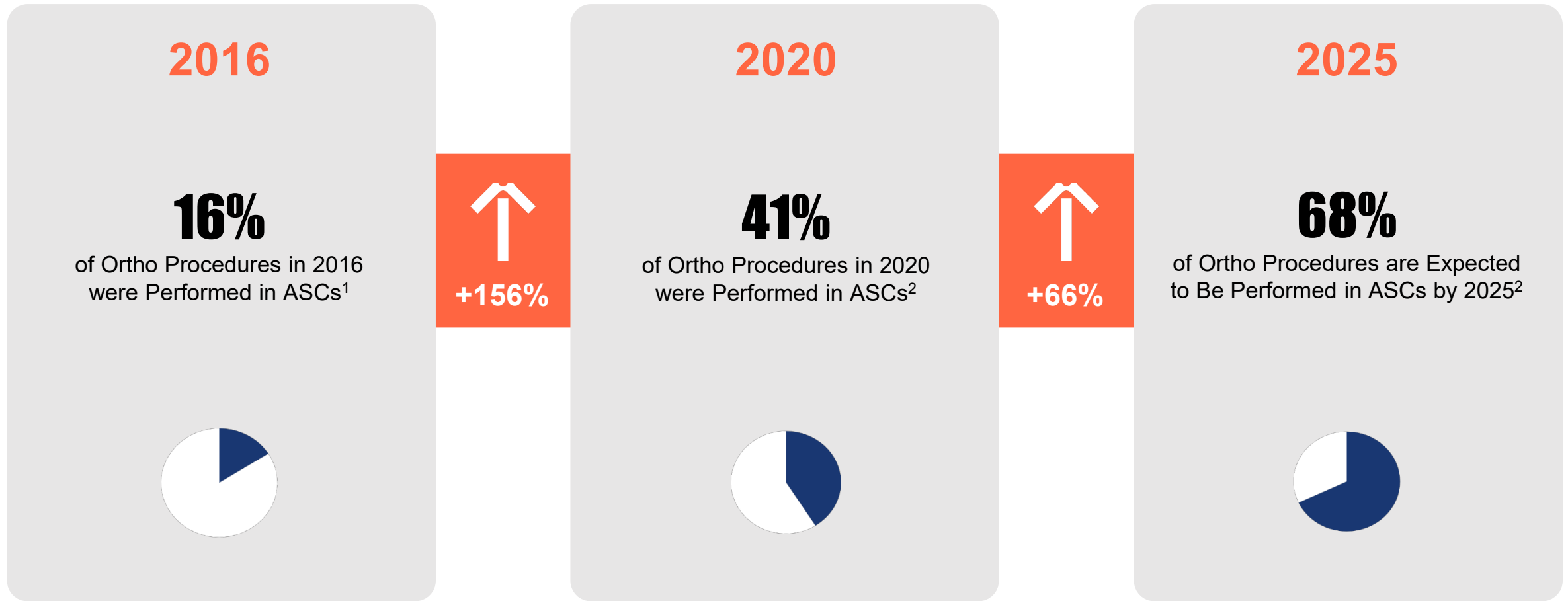
---

## WHEN CHANGE BECOMES IMPERATIVE

---

# Accelerating Industry Tailwinds

Movement of Ortho procedures to ASC's is accelerating, and existing instrumentation is not suitable, nor sustainable for meeting needs





# Addressing ASC Growth

Predictability & throughput benefits in ASC's & Hospitals



## Reusable Model

- Limited capacity in sterilization department
- Slow turnover of OR with instrument prep time
- Risk of delays due to cleaning process



## Single-Use Model

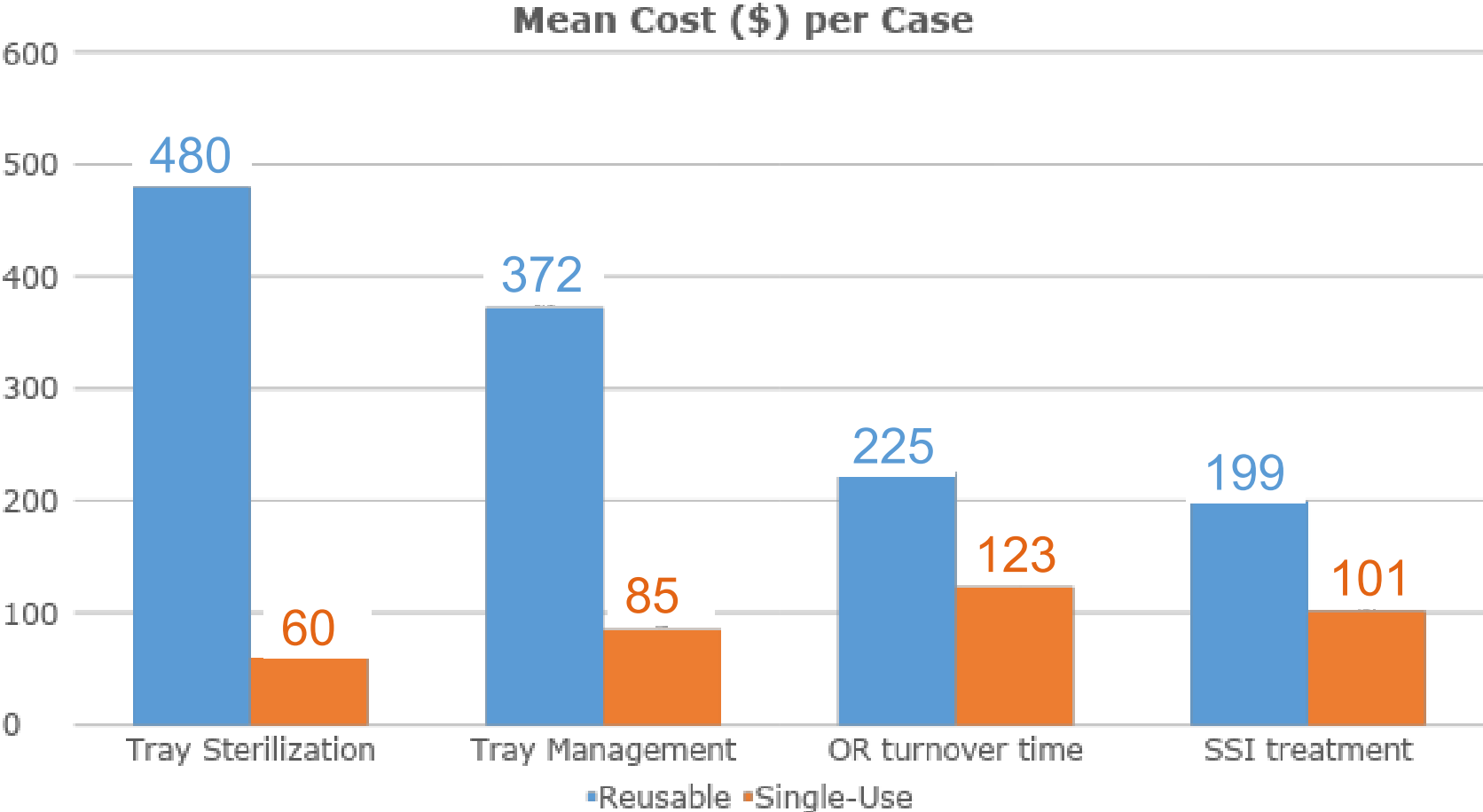
- Rapid OR setup and turnover time
- Reduced delays caused by blue wrap puncture or failed cleaning
- Case volume not limited by sterile processing

# Factors of Single-Use Kit Cost Savings



**\$994**

Cost savings per case for Total Knee Arthroplasty by using Single-Use vs. Reusable<sup>1</sup>



Source:  
1 – Logistical and economic advantages of sterile-packed, single-use instruments for total knee arthroplasty, 2018

# Surgery Site Infection Risks from Reusables

**8.6%**

Contaminated instruments found in sets coming out of sterile processing<sup>1</sup>

**44.4%**

Percent of spine surgeries have >1 hour delay<sup>2</sup>

**2x**

Risk of contracting Surgery Site Infection (SSI) when a case is delay an hour or more<sup>2</sup>

**3x**

Risk of contracting SSI's using reusable instruments versus single use instruments.<sup>3</sup>

Source:

1 – Major Healthcare System & University Study, (Name under NDA) May 2018

2 – Preoperative delay of more than 1 hour increases the risk of surgical site infections, 2013

3 - Value based healthcare: Maximizing efficacy and managing risk with spinal implant technology, 2020

# Functional Benefits of Single-Use



Evidence that exposure to reprocessing cycles leads to increased rates of corrosion, deterioration and damage<sup>1</sup>



Single-use is pristine, sharp, clean and sterile

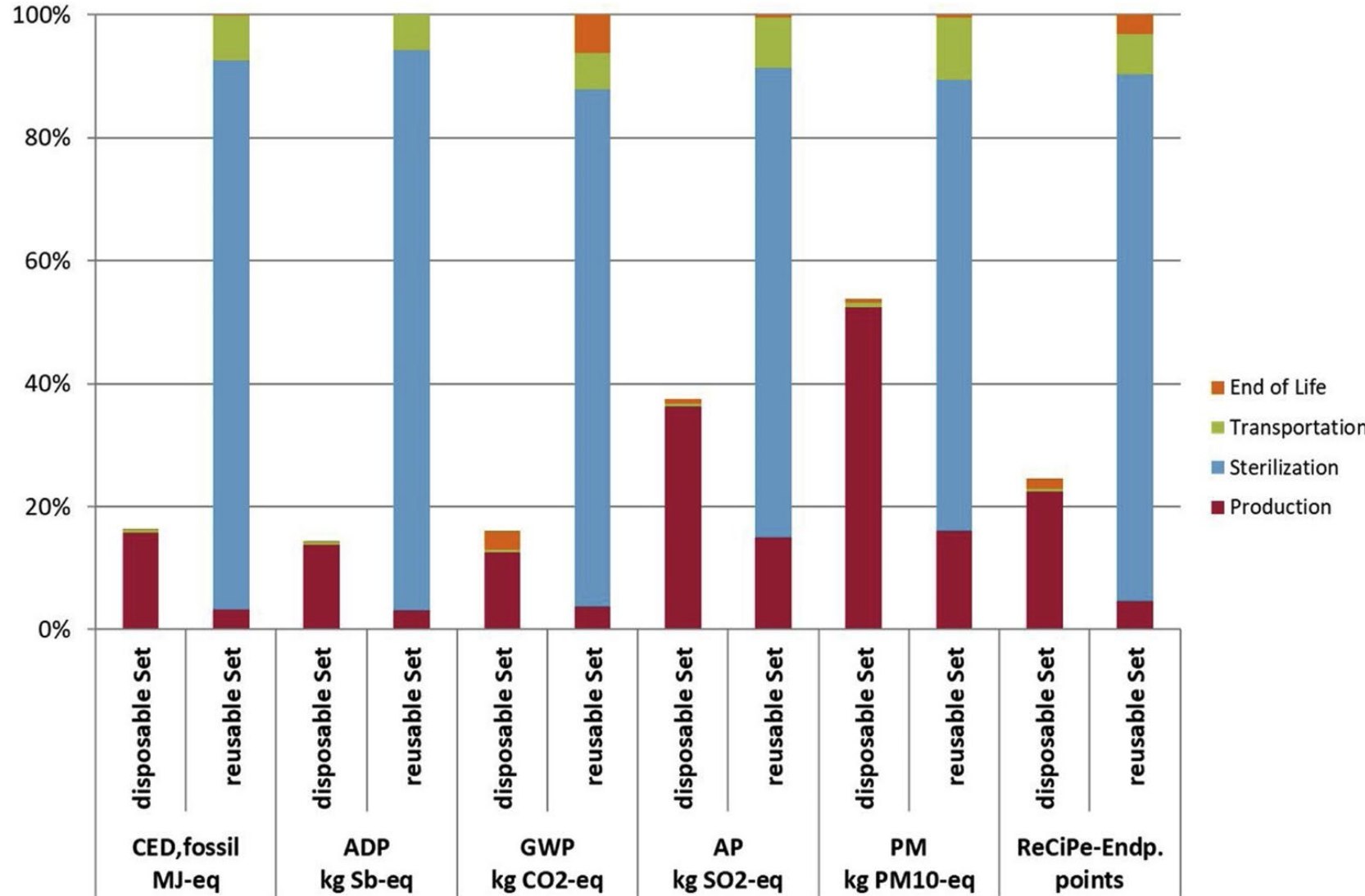


Costly spares, repairs, recalibration and repurchase to facilities and companies

# Life Cycle Assessment

## Reusable vs. Disposable

- 2020 study compared reusable and disposable surgery instrument sets for spine fusion
- Environmental advantage of the disposable sets indicated a benefit of **45-85%** across all impact categories with the single-score indicator depicting an overall benefit of **75%**
- Main drivers were the high environmental impact of the **steam sterilization** and **transportation** of reusable sets



**3**

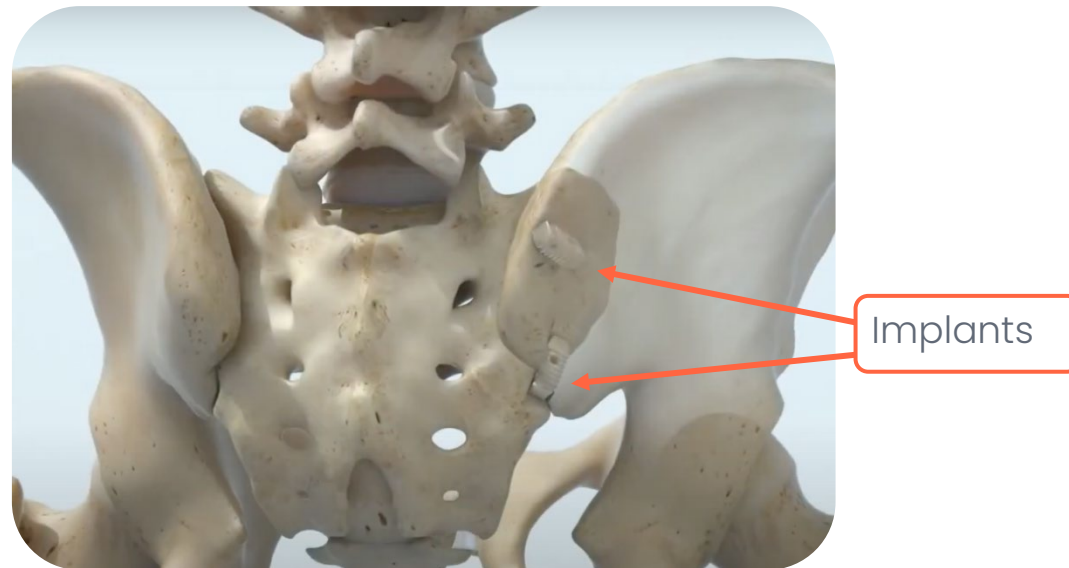
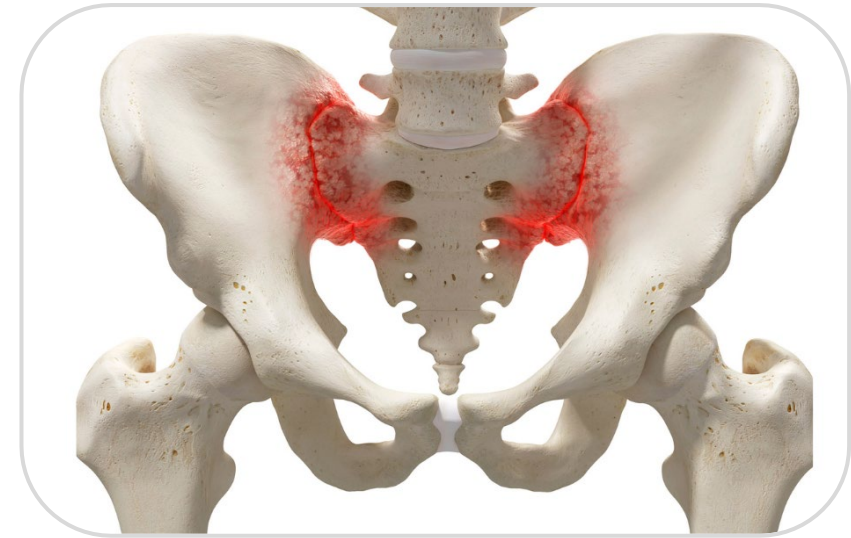
# **Development & Collaboration Case Study**

ECA Medical & Syensqo

# Designing for Single-Use

## SI Joint Stabilization

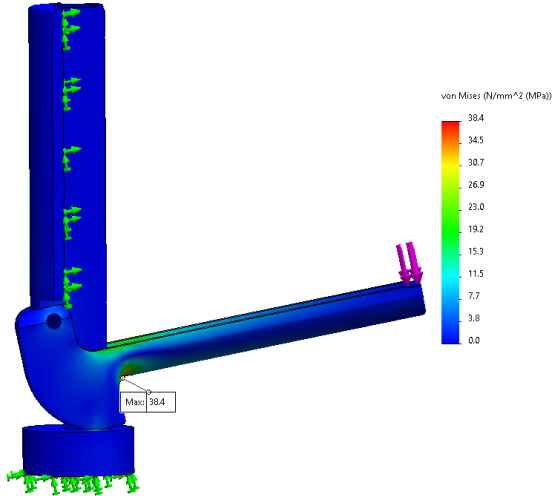
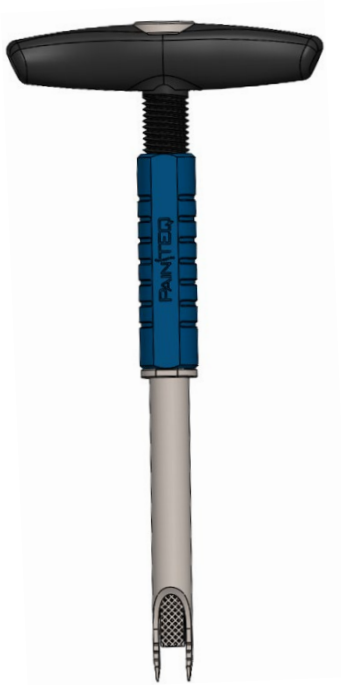
- Effective
- Robust
- Low Cost
- Ergonomic
- Efficient Flow
- Optimize Instrument Set
- Customer Acceptance
- Gamma Stable



# Iterative Development Process

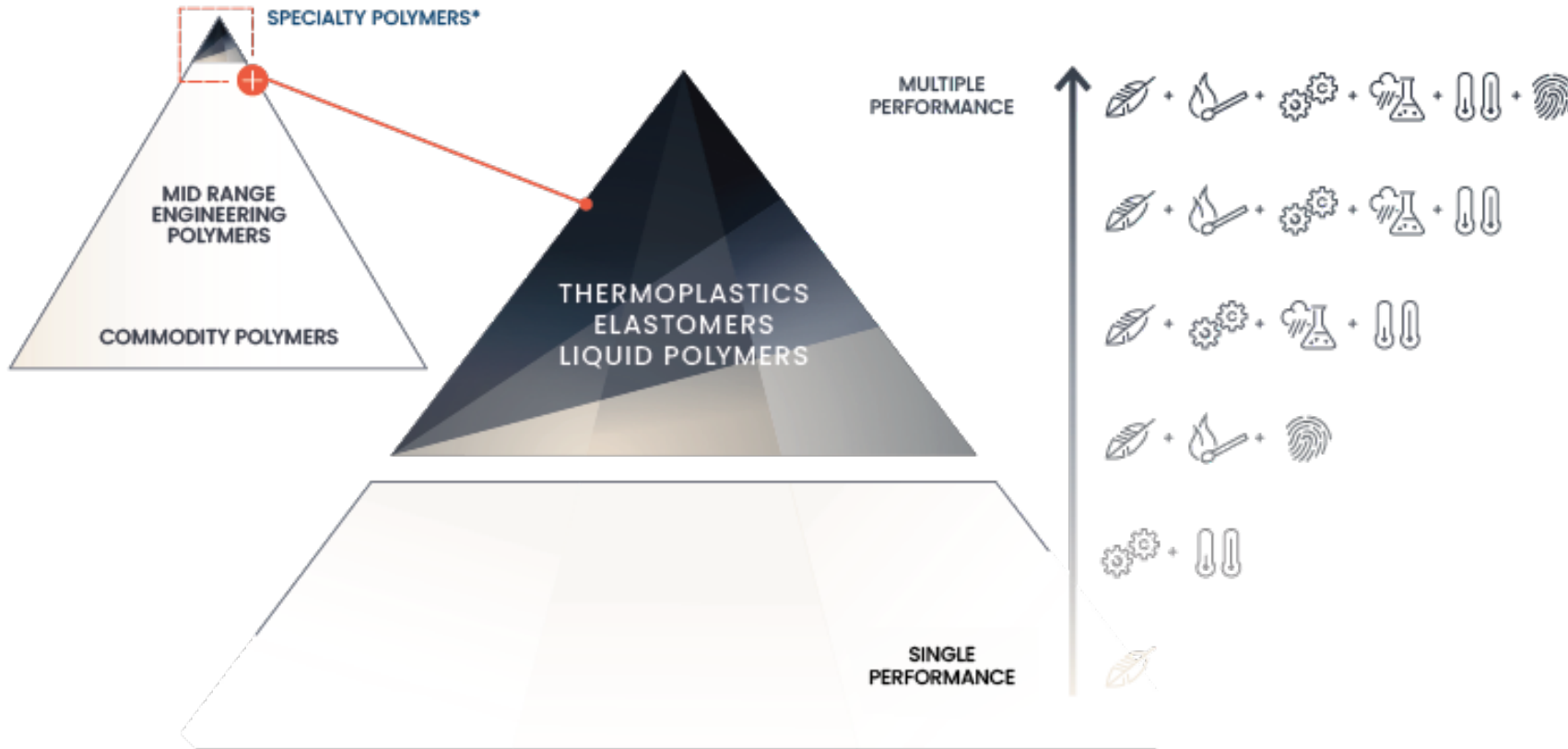
Design Inputs →




Concepts / Material Selection →





# Polymer Material Introduction



-  Light-weighting
-  Fire resistance
-  Mechanical performance
-  Resistance to harsh environments
-  Broad range of temperature
-  Surface properties

# Material Considerations for Healthcare

## High-Performance Plastics

No patient contact Applications

**Amodel<sup>®</sup> PPA**  
**Kalix<sup>®</sup> HPPA**  
**Omnix<sup>®</sup> HPPA**  
**Torlon<sup>®</sup> PAI**  
**Solef<sup>®</sup> PVDF**

## High-Performance Medical Grade Plastics

Limited exposure < 24 hours  
BioPharma (USP Class VI)

- **KetaSpire<sup>®</sup> PEEK**
- **AvaSpire<sup>®</sup> PAEK**
- **Radel<sup>®</sup> PPSU**
- **Udel<sup>®</sup> PSU**
- **Veradel<sup>®</sup> PESU**
- **Ixef<sup>®</sup> PARA HC and GS**

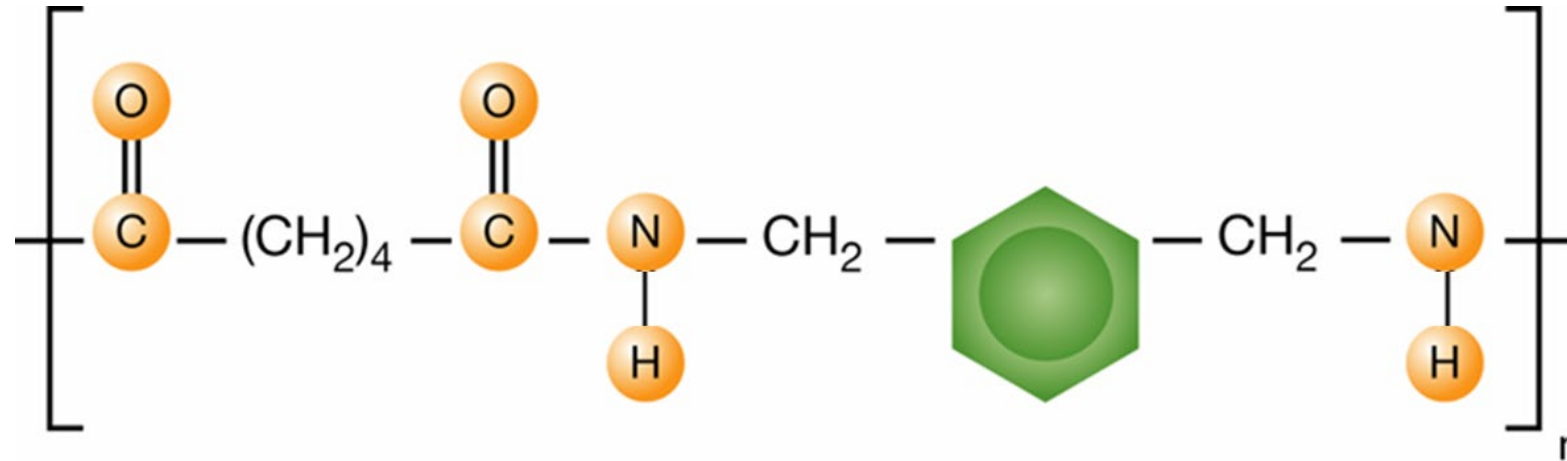
## Solviva Biomaterials for Implantable Devices

Prolonged exposure, 24 h - 30 days  
Permanent exposure > 30 days

- **Zeniva<sup>®</sup> PEEK**
- **Veriva<sup>®</sup> PPSU**
- **Eviva<sup>®</sup> PSU**

# Focus on IXEF<sup>®</sup> PARA

IXEF<sup>®</sup> PARA (Poly-Aryl-Amide) is a semi-aromatic, semi-crystalline composite material of the family of thermoplastics reinforced with glass fibers and/or mineral fillers.



IXEF<sup>®</sup> PARA compounds typically contain 50-60% glass fiber reinforcement, giving them remarkable strength and rigidity. The highest strength/weight ratio of semi-crystalline polyamides. The lowest cost per stiffness unit of semi-crystalline plastics.

# Why Ixef<sup>®</sup>? What makes it so special?

## Excellent resistance to mechanical stresses

- Flexural strength can attain 400 MPa at 23°C.

## Very high rigidity

- Tensile modulus up to 24 GPa at 23°C.

## High thermo-mechanical properties

- Flexural modulus up to 7 GPa at 140°C.

## Very low creep

- Deformation less than 1% after 1,000 hours under 50 MPa at 50°C for certain compounds.

## Very low coefficient of linear thermal expansion (CLTE)

- Values comparable to that of metals.

## Slow rate of water absorption

- Low and slow water pick up in comparison with other polyamides (e.g., PA 6 and PA 6.6).

## Easy processing, also for thin-walled sections

- Good injectability and high productivity even with high fiber content.

## Best flow ability

- Small wall thicknesses (as thin as 0.5 mm) can easily be filled, even with glass loadings as high as 60%.
- Large flow length achievable.

## Excellent surface finish

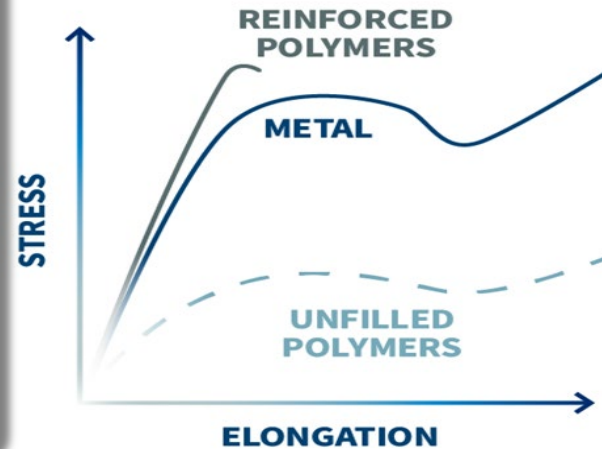
- Superb surface appearance for reinforced products, even with high glass fiber content.

## Low mold shrinkage, highly reproducible

- Precision molding, absence of sink marks and close dimensional tolerances can be achieved.
- Low anisotropic behavior.

# Redesigning with Polymers, What to consider.

- Simulate the current design in metal and test.
- Translate design to plastic and begin modifications to achieve similar behavior, not similar properties.
- Take advantage of CAE and Moldflow analysis to troubleshoot design and manufacturing before production.



- Use the experience and knowledge of skilled molding shops and polymer engineers
- Consider consolidating multiple parts into the new design.
- Take advantage of the best attributes of metal and plastics. Combine the ability to have higher tolerance standardized metal inserts with lower cost plastic structures.

## Remember these simple rules when converting a traditional metal design to a polymer

- Pick your polymer based on whether you want toughness or strength.
- Sharp inside corners are rarely your friend in plastics!
- Not every dimensional tolerance needs to be translated from the metal design.
- Uniform wall thickness = predictable designs



# Designing with Ixef®

## Coefficient of Linear Thermal Expansion

The coefficient of linear thermal expansion (CLTE) of Ixef® compounds is similar to that of many cast metals and alloys.

This attribute also allows for lower stress when over-molding metal inserts.

Material	Direction	CLTE (x10-5 K-1)
<b>IXEF® 1022</b>	<b>Flow</b>	<b>1.5</b>
	<b>Transverse</b>	<b>3.6</b>
Steel		1.2
Brass		1.8
Aluminum		2.4
Zinc		3.0

## Tensile Properties - Comparison to Metals

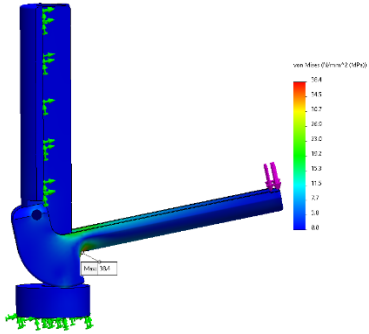
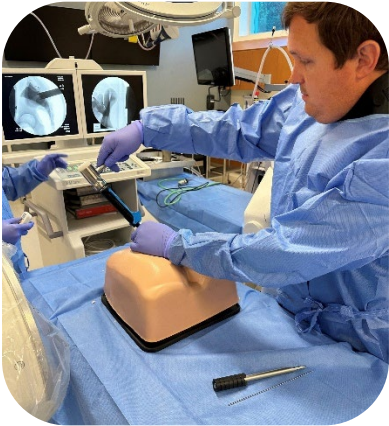
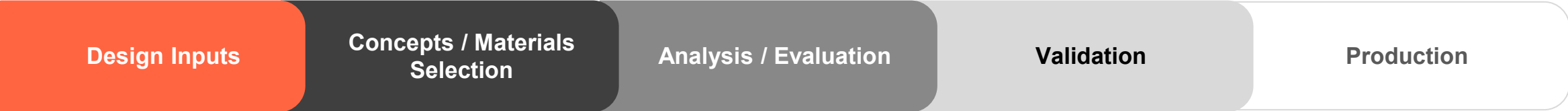
Compared to Aluminum, IXEF® has a reduction factor of 3.5 (considering the elastic modulus) that could be easily solved by design, but with almost a factor of 2 reduction in the density.

This combination of high stiffness and low density, makes, Ixef® PARA the material of choice for metal replacement.

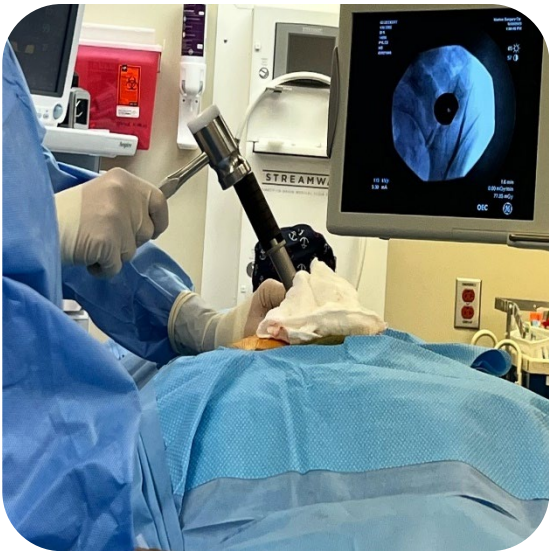
Material	Density (g/cm3)	Tensile Strength (GPa)	E-Modulus (GPa)
Steel	7.8	330	206
Aluminum	2.8	320	70
Zinc Die Cast	6.6	280	70
Magnesia	1.8	225	40
<b>IXEF® 1022</b>	<b>1.65</b>	<b>280</b>	<b>20</b>

Annotations: A bracket labeled "/ 2" spans the density values of Aluminum (2.8) and IXEF® 1022 (1.65). A bracket labeled "x3.5" spans the E-Modulus values of Aluminum (70) and IXEF® 1022 (20).

# Iterative Development Process



# Sacroiliac Joint Kit





# Lessons Learned and Best Practices - ECA

- Get Sales, Marketing and Key Surgeon Opinion Leaders involved early on for the design and configuration input
- Educate the salesforce on single-use benefits and have a marketing strategy to achieve greatest success.
- Do the appropriate testing on the design inputs, don't assume.
- Consider the configuration of an entire portfolio to leverage instrument & packaging designs and validations.

# Lessons Learned and Best Practices - Syensqo

- Designs can be more complex and consolidation is easier due to reduced cleaning validation and procedures
- Use common design features for instrumentation; such as same molded handle with different functional ends
- In metal/plastic hybrid designs; reduce metal design to bare minimum and the simplest design and use plastic to support; such as cutting edges or tight tolerance guide holes
- Consider long term recovery of the instrumentation, most of the devices made from plastic could be returned and reprocessed to other non-medical parts.
- Finally, Get the polymer supplier involved early in the development. Make sure to leverage their expertise in the best practices of polymer design and what to look for and test during validation to make sure you get the most out of the material.

# Questions