



*Safety Syringes, Inc.*  
*Corporate Presentation*

## *Safety Syringes, Inc. – The Early Years...*

<u><i>Date</i></u>	<u><i>Milestone</i></u>
<i>1991</i>	<i>Company founded</i>
<i>1991 – 1994</i>	<i>Developed and patented a broad range of Sharps Injury Prevention devices</i>
<i>1995</i>	<i>Dental aspirating syringe FDA cleared and launched</i>
<i>1997</i>	<i>Company's strategic focus changed to the unit dose, prefilled, glass syringe market</i>
<i>1999</i>	<i>Anti-needlestick legislation implemented in California in July</i>
<i>1999</i>	<i>Launch of UltraSafe® Needle Guards in October</i>
<i>2000</i>	<i>Federal anti-needlestick legislation passed in November</i>
<i>2002</i>	<i>Launch of UltraSafe Passive® Delivery System</i>

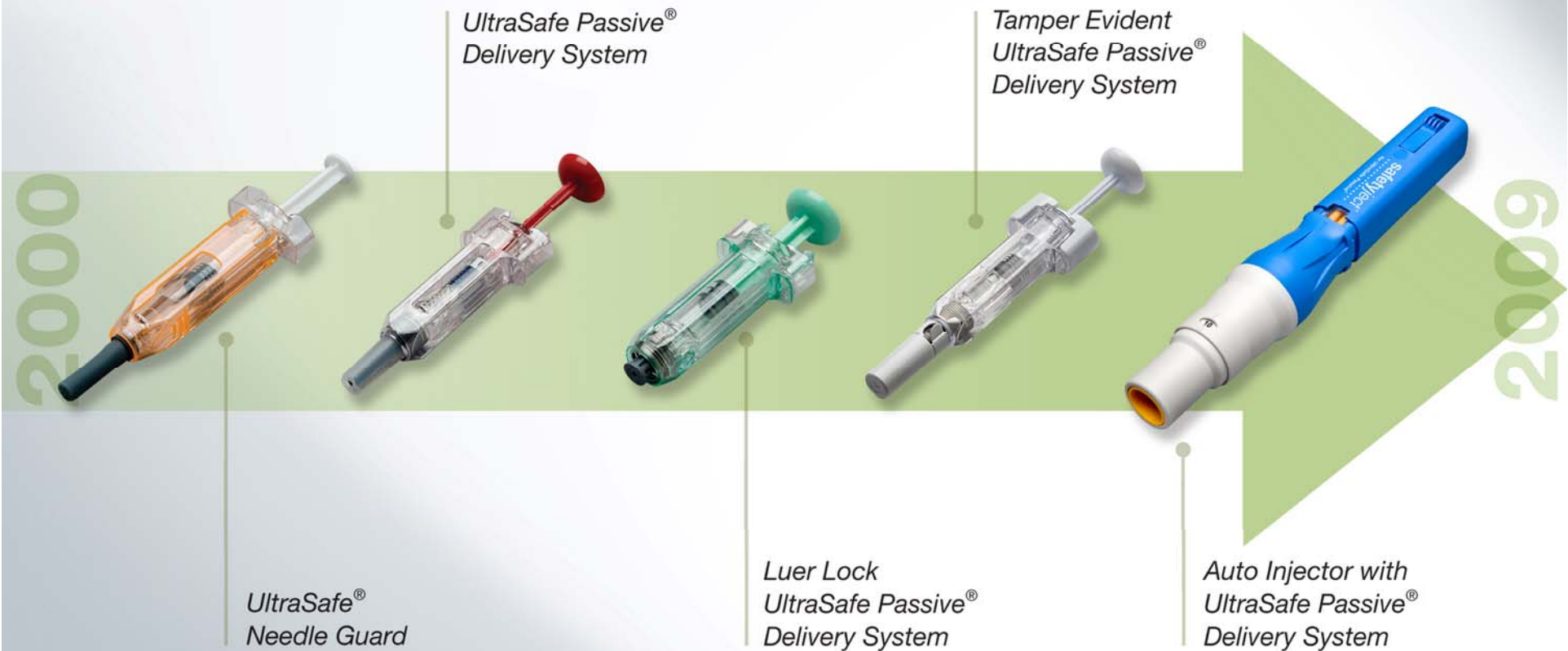
*Global Headquarters  
Carlsbad, California USA*





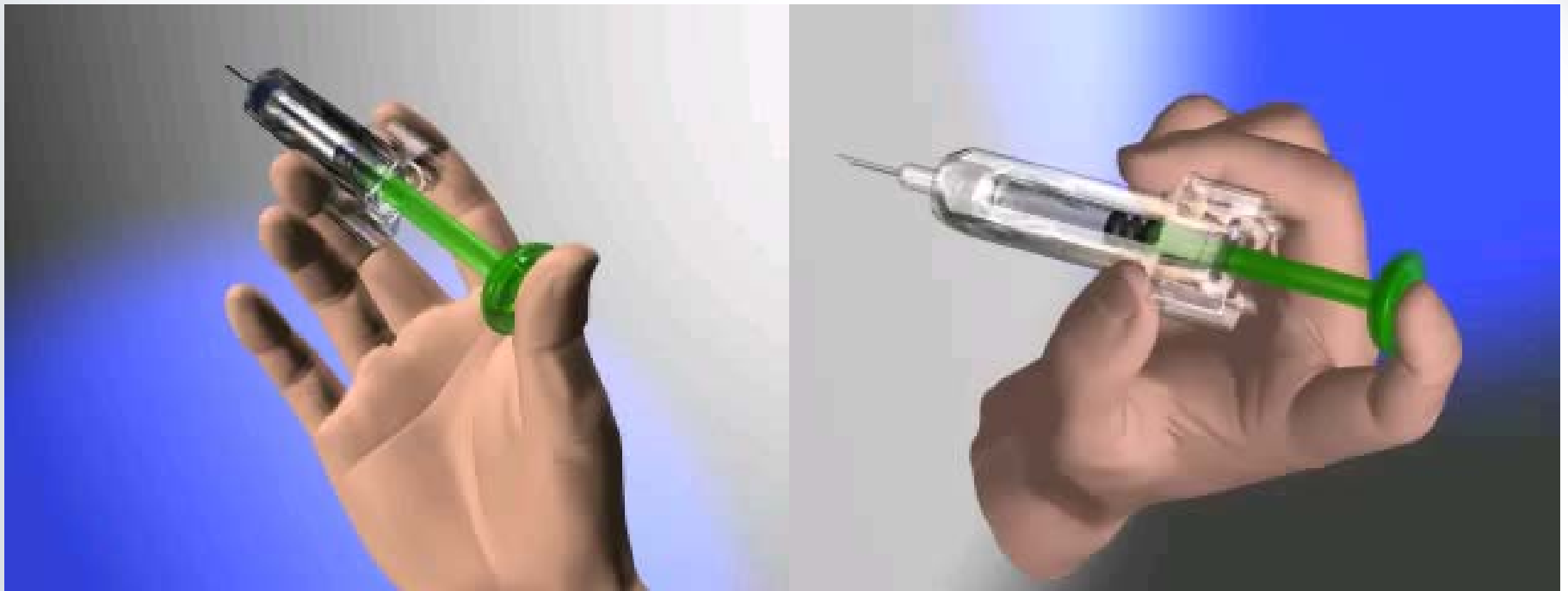


# *From Needle Safety to Better Drug Delivery Systems...*

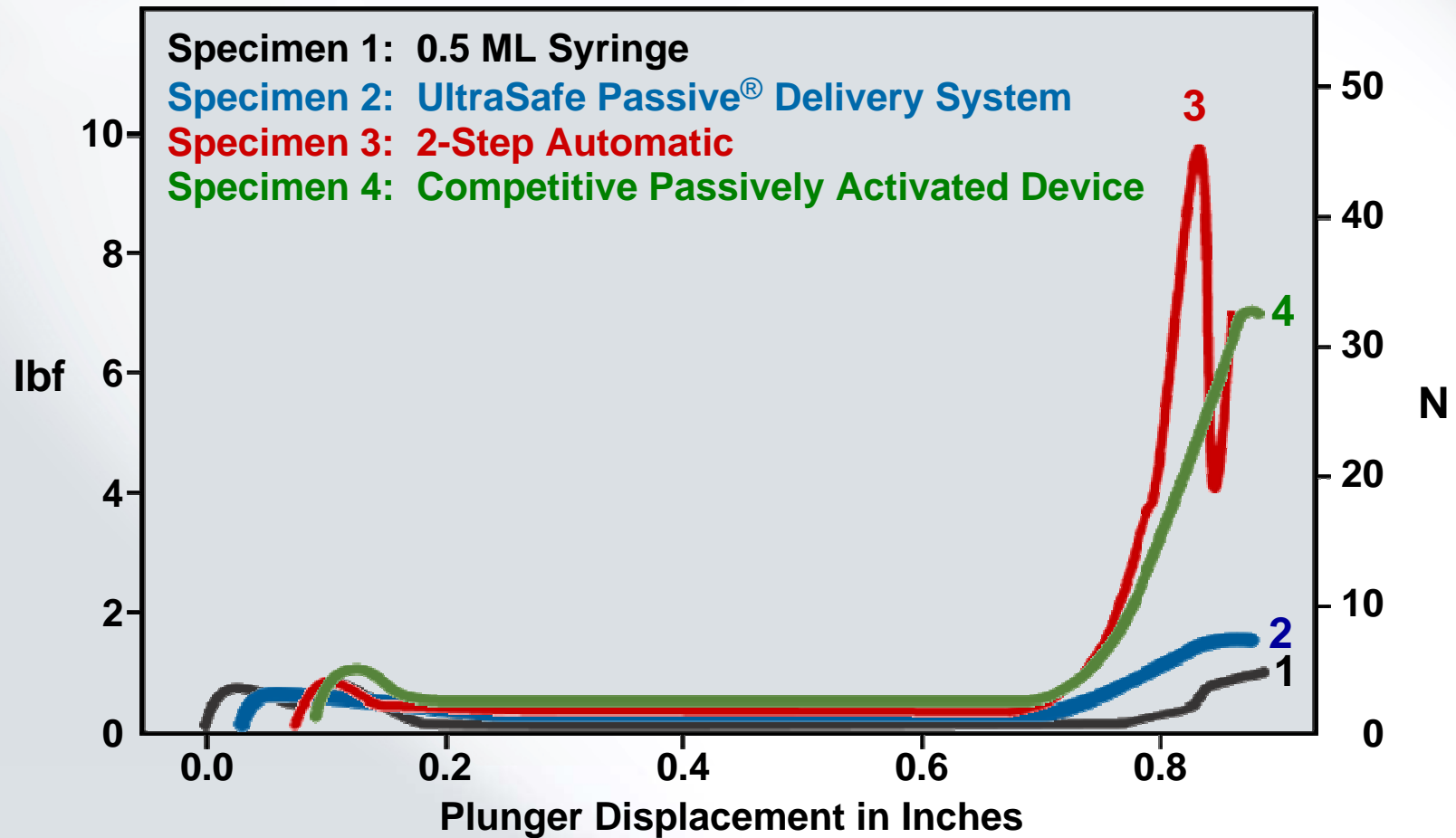


## *UltraSafe Passive<sup>®</sup> Delivery System*

*With each injection, ensure user compliance,  
protection and ease of use*

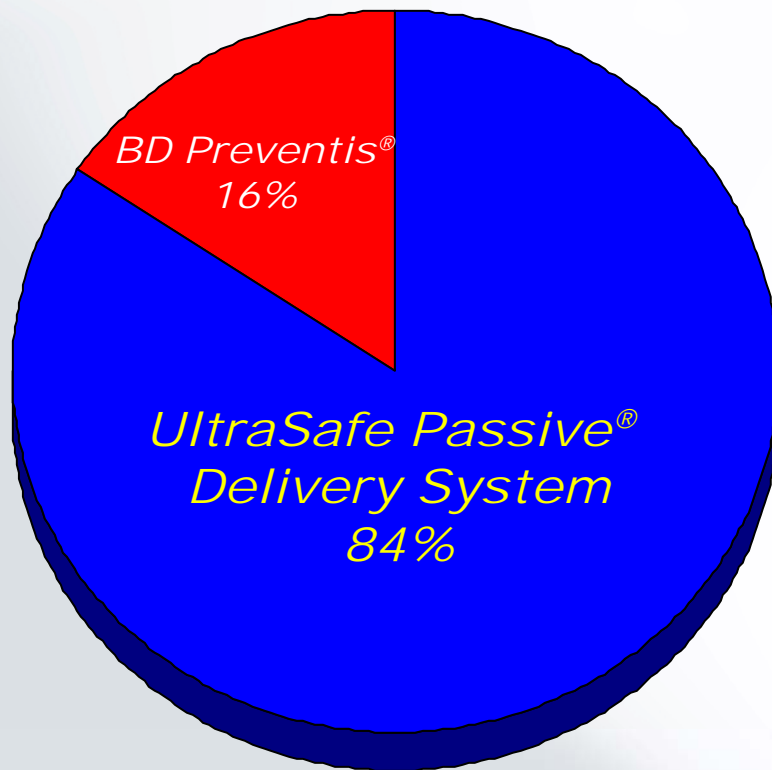


# Force Required to Deliver Medication and Activate Safety Mechanism



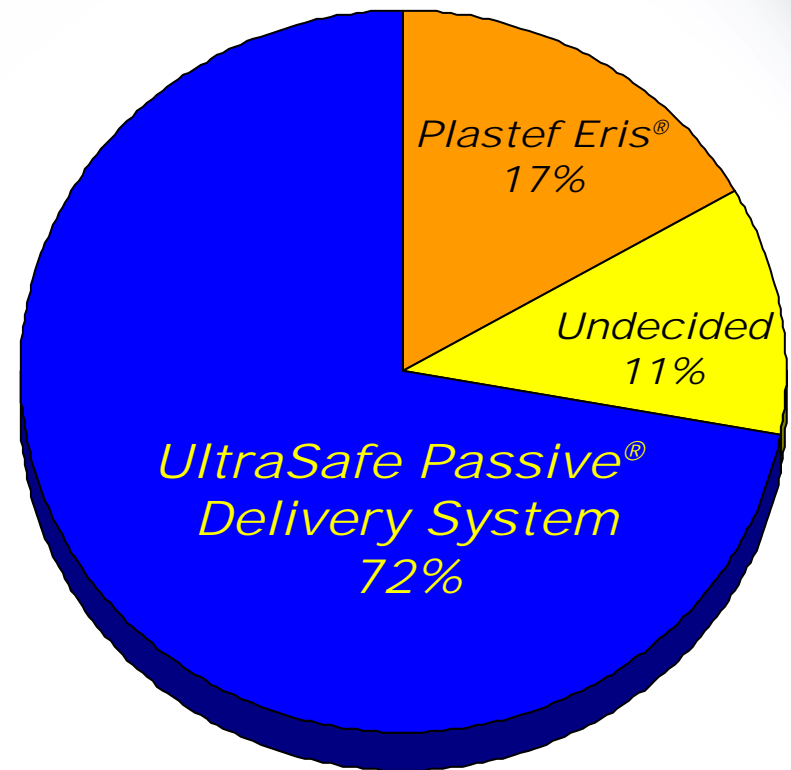
## Users Prefer UltraSafe Passive® Delivery System to Other Devices

UltraSafe Passive vs. Preventis



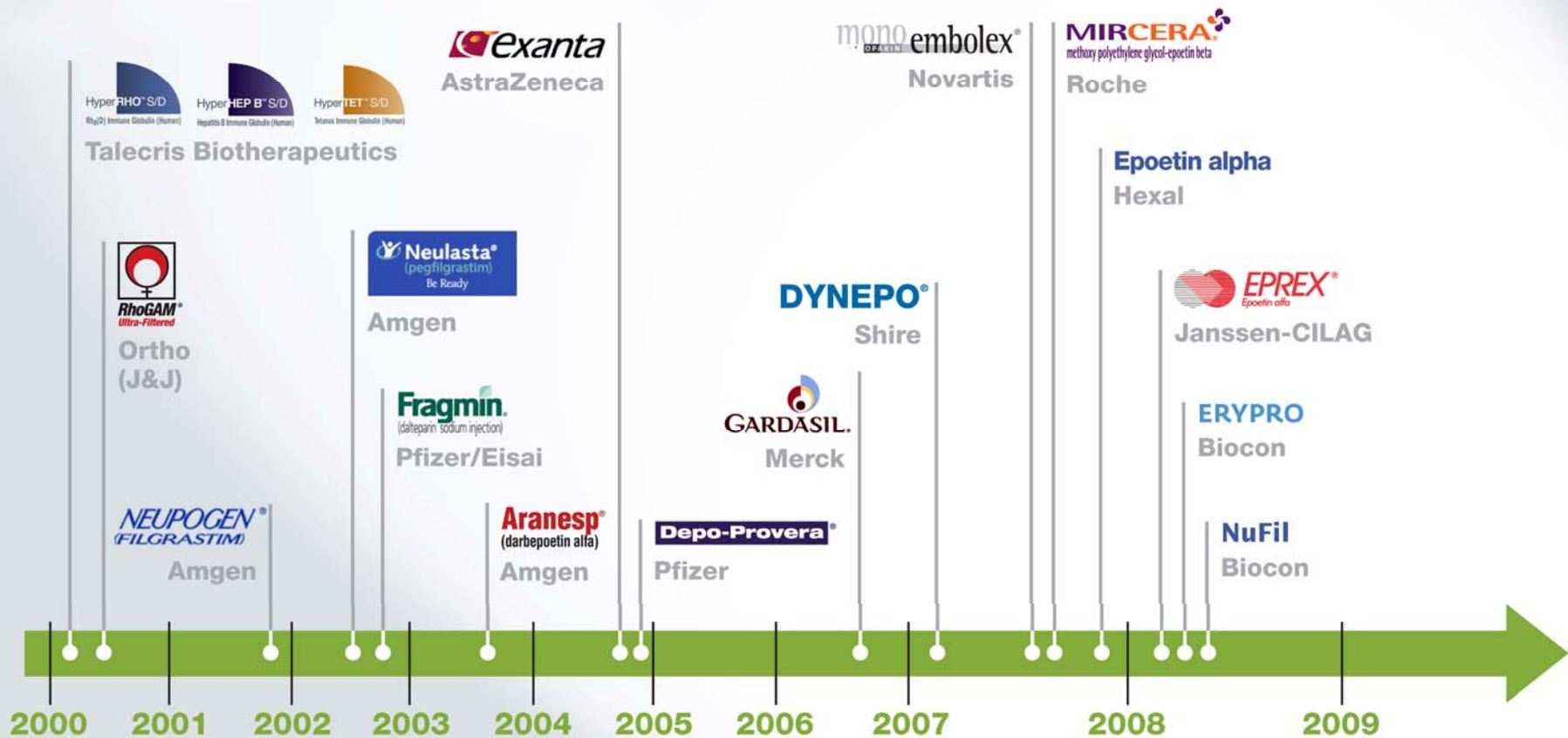
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UltraSafe Passive vs. Eris

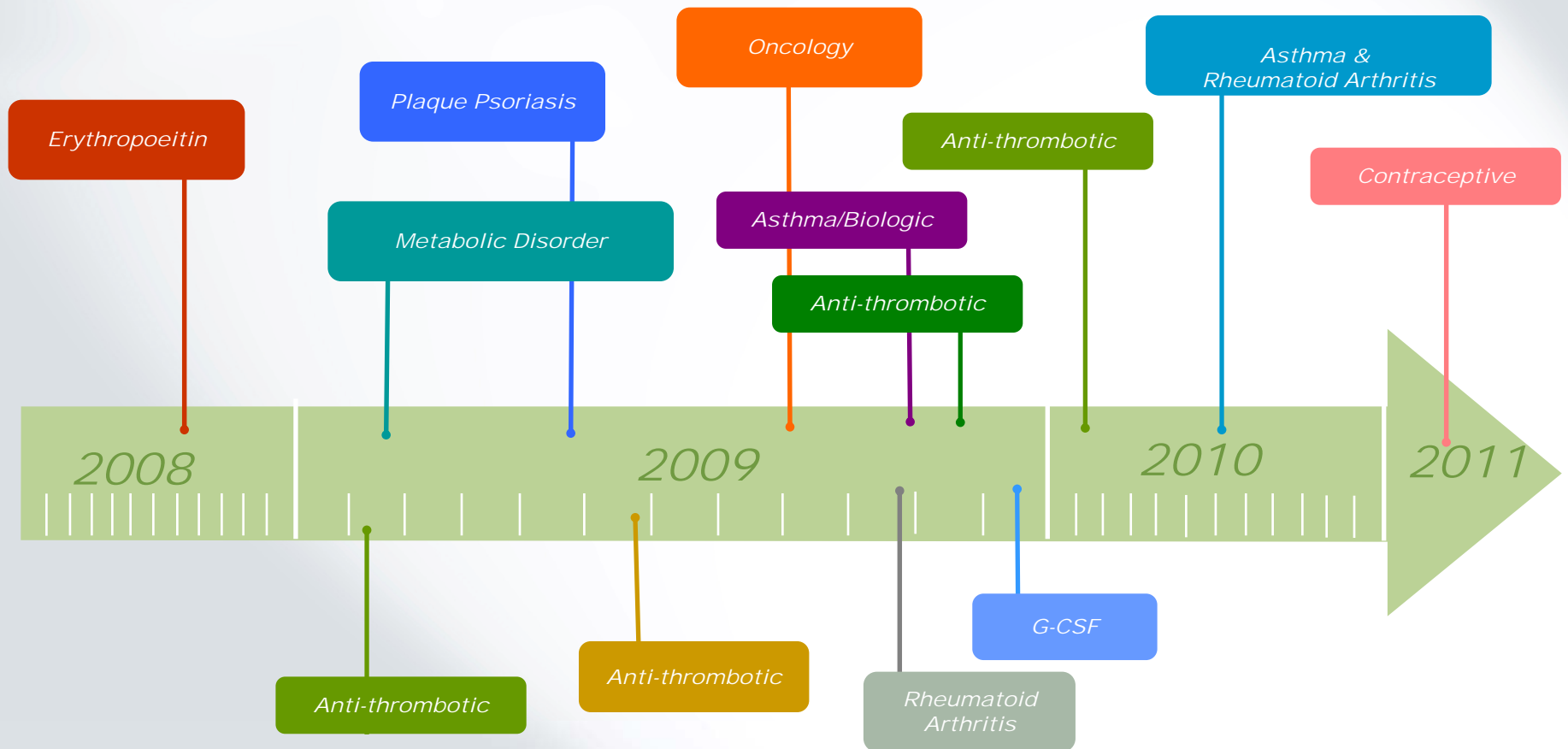


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# Products Marketed with an UltraSafe® Device



# Upcoming Product Launches with the UltraSafe Passive® Delivery System



## *Broad Intellectual Property Ensures Your Freedom to Operate*

### *Intellectual Property Position*

- *26 US and International patents issued; multiple patents pending*
- *Most recent patents protect UltraSafe Passive® Delivery System*



## *Extensive Product Options Allow for Customization and Brand Identity*

*Engineered to accommodate a wide range of glass syringes*

- *Fits ISO standard glass syringes*
- *Accommodates glass syringes from 0.5mL to 2.25 mL*
- *Luer lock and luer slip configurations*
- *Tamper Evident feature*
- *Auto Injector with the UltraSafe Passive® Delivery System*
- *Custom engineering/branding*
  - *Logos, printing, colors and custom tooling available*

## *Seamless Integration into Pharmaceutical Packaging Lines*

- *Shortest time to market*
- *Assembly Automation and packaging systems*
  - *Partnerships established with leading secondary packaging and automation machine builders*
  - *Partnership with labeling company providing tear-off label technology on primary container*
- *Product packaging support*
  - *Tested and validated for distribution*

## *The Highest Product Quality Standards*

- *ISO 13485: 2003 Certified*
- *All devices are 510(k) cleared*
- *All products are CE marked*
- *cGMP compliant facilities and processes*
- *Products exceed all FDA\*, NIOSH\*\*, and GERES\*\*\* guidelines for design features*



*\* Published 1995; \*\* NIOSH (National Institute for Occupational Safety and Health) 1999 Alert "Preventing Needlestick Injuries in Health Care Settings; \*\*\* GERES (Groupe D'étude Sure Le Risque D'exposition des Suignants aux agents infectieux, Guide des Matériels de Securite 2004*

## Needle Safety Mandate in Germany

- *Technical Rules for Biological Agents, Biological Agents in Health Services and in Welfare Care*
- *Relevant Section 4.2.4.*
  - *In order to protect employees from injuries caused by pointed and sharp medical instruments, these instruments must be replaced with such suitable safe work tools - to the extent technically possible, which do not pose any or very small risk of a jabbing or cutting injury*
- *Effective date is August 1, 2007*



Berufsgenossenschaftliche Regeln für Sicherheit und Gesundheit bei der Arbeit  
BG-Regel

BGR 250/  
TRBA 250

Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege

vom Juli 2006

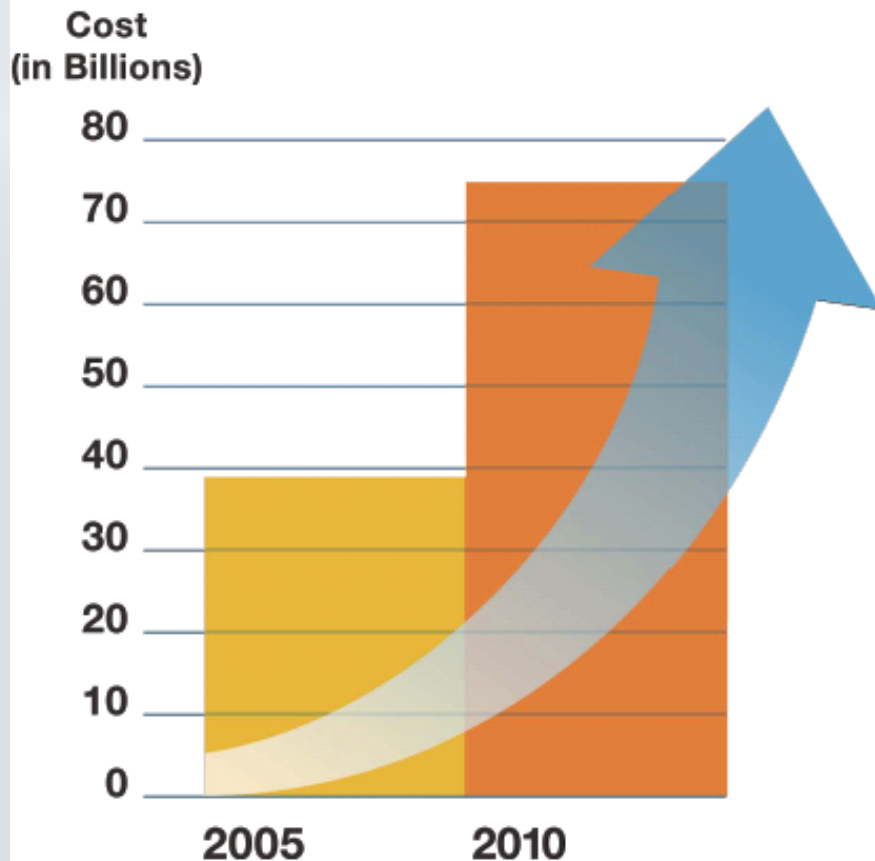
Fachausschuss „Gesundheitsdienst und Wohlfahrtspflege“ der BGZ

HVBG  
Hauptverband der gewerblichen Berufsgenossenschaften

## *Needle Safety Mandate in Germany*

- *Effective August 1, 2007*
- *It is a “Must” regulation*
- *Applicable to hospitals and physicians’ offices*
- *Exceptions to this sharps injury prevention regulation are ‘risky’ and difficult to realize*
- *Performance requirements for needle safety devices*
  - *One handed activation*
  - *Shall not require change in technique*
  - *No re-use possible*

## Counterfeit Drug Trade – A Growing Global Problem



Source: Center for Medicines in the Public Interest  
Report, September 20, 2005

- *Counterfeit drugs are a lucrative business*
  - \$39 Billion in 2005
  - \$75 Billion by 2010 (est.)
  - Loss to pharmaceutical companies is multi-fold greater
- *Counterfeiting is “Big Business” for Criminal Networks*
  - Increased sophistication in technology and speed

## *Tamper Evident UltraSafe Passive® Delivery System*



### *Tear-away needle cap*

- *Must be removed to access the needle shield*
- *Needle cap secures the drug content from packaging to the patient*

## *Tamper Evident UltraSafe Passive® Delivery System*



### *Secured back plate*

- *Plunger cannot be removed without damage to the back plate*
- *Back plate prevents access to drug content*

## *Tamper Evidence Benefits Your Brand*

- *Easy to recognize signs of tampering*
- *Differentiates your brand*
- *Prevents product loss*
- *Reduces risk and liability*



*From the clinical setting...*



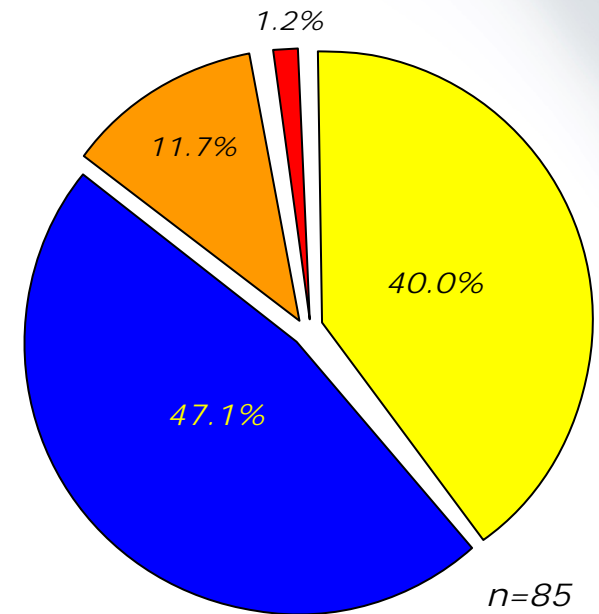
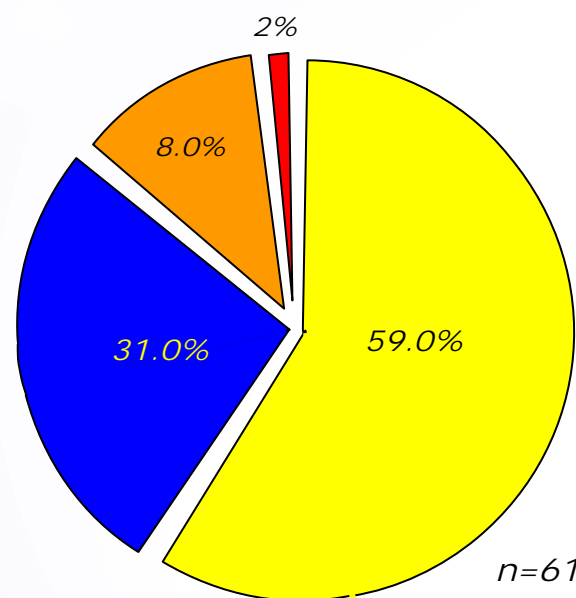
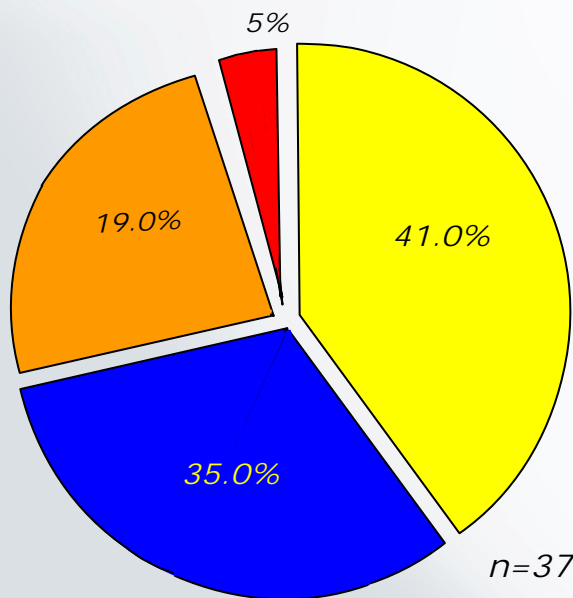
*...to self-administration*



# Self-Administration Market Research

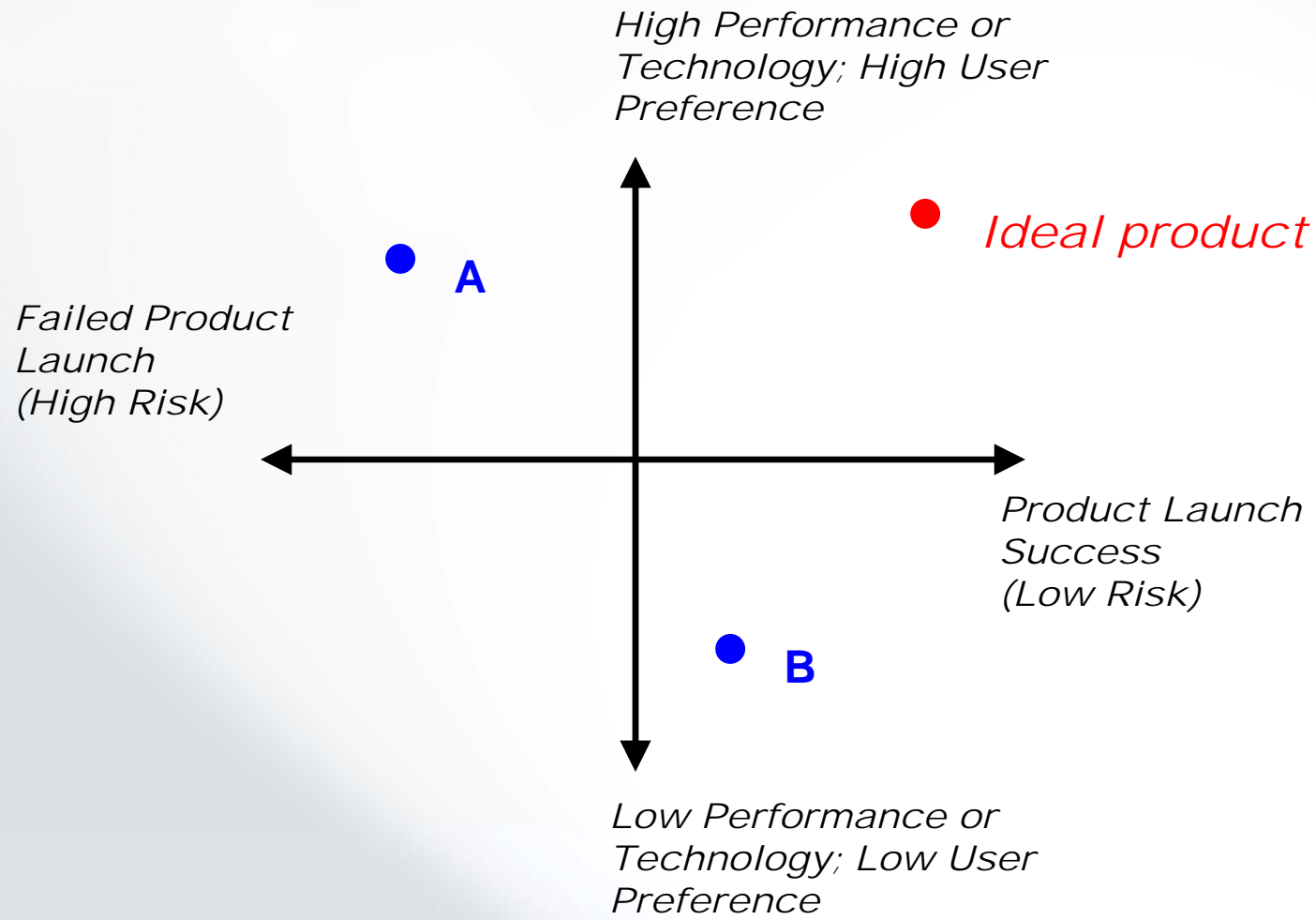
MS Patients

Oncology Patients



- UltraSafe Passive® Alone
- UltraSafe Passive® with Auto Injector
- Conventional Syringe Alone
- Conventional Syringe with Auto Injector

## Pharmaceutical Company Considerations for a Successful Product Launch



# Thank You

760.918.9908 [www.safetysyringes.com](http://www.safetysyringes.com)