



New Product Introduction:

Eagle Medical's role in the WCSA Roadmap to product launch





Where does Eagle Medical fit in the ecosystem of medical device launch?

1

Stage 2 (Design and Prototype) & Stage 3 (Pathway to Approval):

- Product Development and Prototyping Support
- Packaging Design & Validation
- Contract Manufacturing of Devices (Assembly & Test)
- Sterilization Validation & Management

2

As well as Routine Production:

- Build to Stock: Cleaning, Packaging & Labeling
- Palletization/Preparation for Distribution
- Materials & Supply-Chain Support & Procurement

Packaging Design/Validation Support

Standard Distribution Testing is the Baseline:

- Keep the contents clean
- Make it self-explanatory and easy to open (better than IKEA)
- Keep the contents sterile
- Make it impossible to accidentally open

WPB: Eagle Medical and others
8 – 12 weeks

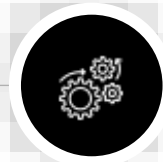


Package Design

Quality design = a great first impression

- Sterile barrier
- Packaging system
- Labeling
- Box math

Eagle Medical
3 – 4 weeks



Process Validation

- Sealer settings
- OQ, PQ

WCDA partner Westpak
3 – 4 weeks



Distribution Testing

- Environmental Conditioning
- Distribution Simulation

Eagle Medical & Westpak
4 – 6 weeks



Aging Studies*

- Accelerated Aging
- Real-Time Aging

Traditional Packaging Validations take 10 – 30 weeks to complete

*Aging timeline(s) based on 1-year accelerated studies only. 3-year and 5-year time-periods are commensurately longer.

Sterilization Validation Support

(takes place sequentially after packaging validation)

Sterilization Validations can take many months to complete...without Eagle's know-how

EO Large Batch

1

- Inexpensive
- Protracted Validation Timeline
- Severe Capacity Issues
- Long production lead-times

Sterigenics (non-WCDA)

EO Small Batch

2

- Expensive
- Reduced Validation Timeline
- Minimal Capacity Issues
- Manageable Lead-times

WCDA: Blueline

Irradiation

3

- Inexpensive
- Typical Validation Timeline
- Available Capacity
- Twice/Week Sterilization Runs

WCDA: SteriTek

VH2O2

(now FDA 'established category A')

4

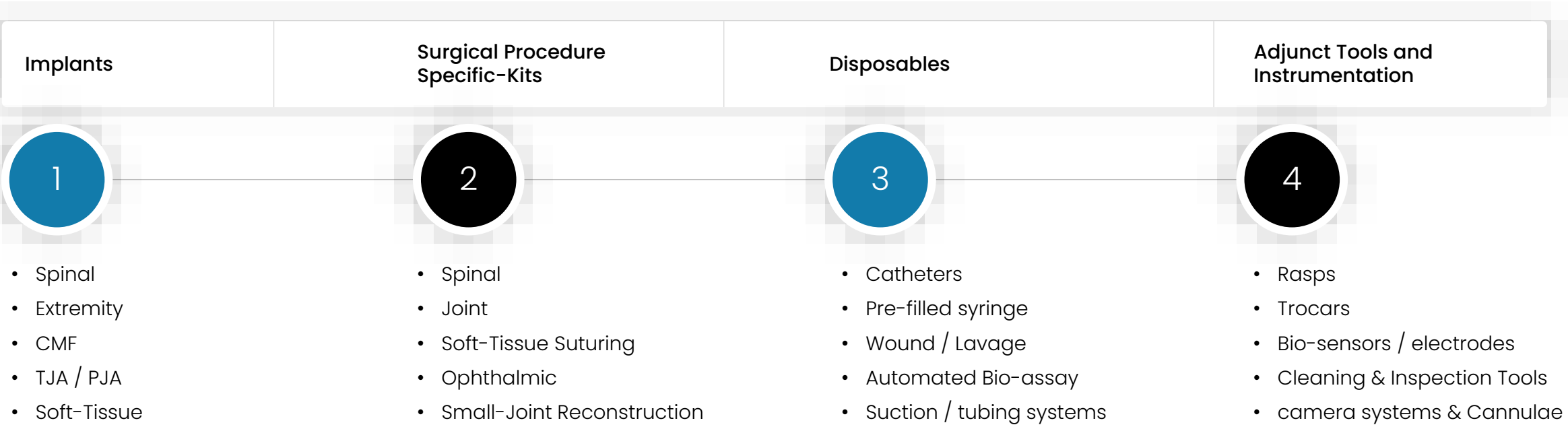
- Moderately Expensive
- Shortest Validation Timeline
- Available Capacity
- Shortest Lead-times

WCDA: Eagle Medical

To gain an uncommon advantage, be sure to ask about our EO Dual Validation Pathway.

Assembly & Testing

Types of product Assembly:



And yes, Eagle can validate your product-specific fixture/assembly

Budgetary Pricing* Bookends

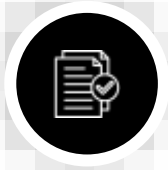
Total Packaging and Sterilization Validation Costs: \$50K – \$200K



Package Design

- Simple e.g.: pouch w/backer-card
- Moderate e.g.: multi-unit custom tray
- Complex e.g.: full custom multi-tray

\$20K – \$100K+



Process Validation & Distribution Testing

Typically includes:

- Sealer Validation
- OQ/PQ:
- Climatic Conditioning & Distribution Simulation

\$23K – \$36K



Aging Studies

- Includes Accelerated and Real Time Aging. Variables include: One or multiple shelf-life targets, chamber volume required, days in chamber

\$4K – \$20K



Sterilization Validation

Typically includes:

- Ethylene Oxide
- Irradiation (gamma, e-beam, x-ray)
- VH2O2 / VHP
- Chlorine Dioxide
- Other

\$20K – \$35K+

*Prices shown are for explanatory purposes only; your project specifics will define actual pricing ranges and ultimate firm pricing

Eagle Medical Execution Advantages

Services Unique to Eagle Medical:



PATH®

- True-Validated® packaging system is fully pre-validated
- Includes a submission-ready document set

~3 Weeks to FDA
Submission Ready
Packaging Validation



West Coast Device Alliance

- Alliance partners offer priority lead-times
- The WCDA Onboarding Roadmap provides clarity of supplier pathway
- Readiness Checklist accelerates onboarding timeline

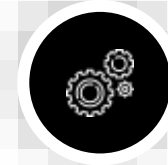
Your Go-To-Market
Alliance



In-house VH_2O_2 Sterilization

- Now FDA 'established category A'
- Short lead-times and available capacity
- Environmentally friendly/no toxic off-gassing

Fast, Safe, Available
Capacity



In-house Tyvek Conversion

- Customized NPI-level pouch manufacturing
- Customized NPI-level backer-card manufacturing
- Tyvek pouches and lid-stock available for samples and initial production runs

Supply Chain Problem
Solvers

When time to market matters, trust Eagle to get you there first

Contact Us:



(805) 238-7401



info@eaglemed.com



<https://eaglemed.com/>

