

## SOLUTION SHOWCASE

### Innovative Drug-Eluting Implants

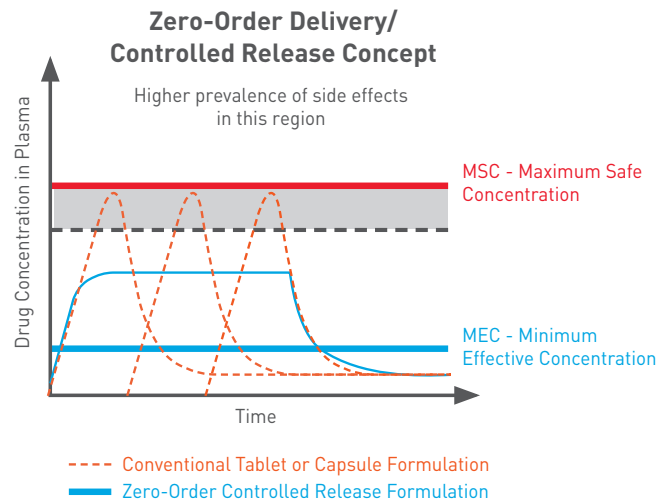


Vitaldose® EVA is an enabling technology formulators can leverage to create effective implants for long-acting controlled release therapeutics

#### PROVEN SOLUTIONS

##### Ease of Formulation:

- Vitaldose® EVA is a platform compatible with biologics, peptides, and small molecules.
- Many implant designs are possible ranging from single phase to co-continuous structures. Monolithic as well as multilayer constructions are possible.
- Furthermore, formulators have the flexibility to incorporate additional inactive ingredients required for a particular design.
- Vitaldose® EVA is compatible with various manufacturing platforms including micronization, blending, hot melt extrusion, injection molding, and spray dispersions.



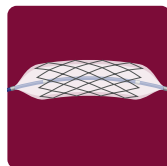
##### Vitaldose® EVA product form factors



Injection molded and extruded form



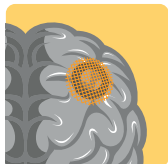
Extruded films for transdermal patches



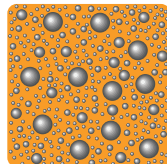
Drug-eluting coatings



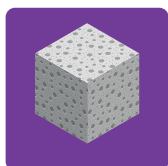
Injectable fibers for ophthalmic implants



Filaments and coatings for meshes



Microparticles



Foams and/or porous substrates



Injection molded geometries for surgical implants

##### Reliable Performance:

EVA is a durable polymer best suited for more critical applications.

- When the ability to interrupt therapy is required, EVA based implants can be reliably retrieved
- EVA is a biostable polymer. This results in better control of the dosing and eliminating undesirable bursts.
- Very high drug loadings (>75%) is feasible with EVA, enabling longer term applications
- EVA is a durable polymer and is ideal for longer-term, more critical applications.
- Vitaldose® EVA can be reliably retrieved to interrupt therapy when required.





## SOLUTION SHOWCASE

### Innovative Drug-Eluting Implants

**VITAL Dose**<sup>®</sup>



#### PROVEN SOLUTIONS

- Vitaldose<sup>®</sup> EVA has a well-established regulatory profile. It is currently used in marketed products, clinical trials, and being developed for a number of new indications. It is listed the FDA inactive ingredients list and Celanese has registered drug master files.
- Many types of dosage forms have been developed with EVA: subcutaneous and surgical implants, intravitreal and extraocular devices, intravaginal rings and oral.

#### Mixing Processes

- Melt mixing
- Solution
- Emulsion
- Impregnation

#### Melt Processes

- Compression molding
- Injection molding
- Blow molding
- Extrusion

#### Solution Processes

- Spraying
- Dipping
- Spin coating

#### REGULATORY SUPPORT

Vitaldose<sup>®</sup> EVA has been approved for use in numerous pharmaceutical and medical device applications around the world.

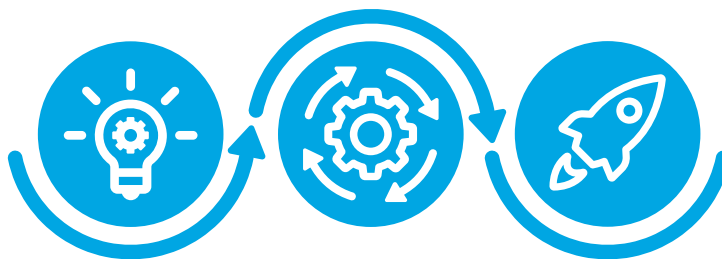
Drug Master Files and technical support are available for customers' regulatory approval.

Vitaldose<sup>®</sup> EVA excipients are manufactured according to agreed manufacturing practices that align with GMP requirements.

Celanese provides various certifications including, but not limited to:

- USP Class VI biocompatibility
- European Pharmacopoeia certification
- ISO 10993 biocompatibility
- Drug master file listed
- Acute Oral Toxicity tested
- FDA food contact
- European food contact
- REACH compliant

### From FEASIBILITY to DEVELOPMENT to COMMERCIALIZATION



Our scientists and engineers are there from concept to commercialization, providing development services, GMP material supply and regulatory support. Our objective is to help our customers reduce time and risk in research and development, so their drug achieves a higher chance of success.

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#### Contact Information:

Website: [healthcare.celanese.com](http://healthcare.celanese.com)

#### Americas

8040 Dixie Highway, Florence, KY 41042 USA  
Product Information Service  
t: +1-800-833-4882 t: +1-859-372-3244

#### Europe

Am Unisys-Park 1, 65843 Sulzbach, Germany  
Product Information Service  
t: +(00)-800-86427-531 t: +49-(0)-69-45009-1011

Email: [healthcare@celanese.com](mailto:healthcare@celanese.com)

Customer Service  
t: +1-800-526-4960 t: +1-859-372-3214

#### Asia

4560 Jinke Road, Zhang Jiang Hi Tech Park  
Shanghai 201203 PRC  
Customer Service  
t: +86-21-3861-9266 f: +86-21-3861-9599