Boulder iQ Innovation to Quality | Boulder Sterilization

# Boulder iQ Bulletin

January 2023

## PACKAGING and STERILIZATION

Introducing the Boulder iQ Bulletin, where we'll be sharing focused content each month. In this edition, we focus on packaging and sterilization, with an overview on our packaging services, an article on rapid prototyping materials and their compatibility with sterilization, and a packaging success story with Hubly Surgical. And be sure to check out some of our past articles on a variety of packaging and sterilization topics.



## BOULDER iQ PACKAGING SERVICES

**In-house packaging, labeling and validation**
Boulder iQ offers in-house packaging, labeling and validation. Services include tray and pouch sealing and validation within a Class 10,000 clean room (Class 7-equivalent controlled environment). In-house labeling and secondary packaging assure that each product is customer-ready. Boulder iQ also provides ISO 11607 packaging validation work for terminally sterilized devices, including the development, execution and delivery of protocols and reports.

Boulder iQ engineers provide packaging design and redesign services for user efficiency and effectiveness, and cost reduction. And with all services under one roof – including assembly – customers eliminate the need to juggle multiple vendors, and gain the efficiencies of simpler project management and coordination.

**FAQ**
**1. Can you do packaging, labeling and validation – as well as assembly? Or do I need to work with a separate vendor for assembly?**
We can provide all services – including assembly. We can handle packaging testing in-house, too: peel strength, bubble leak, dye penetration and visual inspection. No need to manage multiple vendors. You'll gain the efficiencies of simpler project management and coordination which translate into a cost savings.

**2. What about distribution?**
We conduct shipping validations and can handle all your distribution needs.

**3. Will I need to contract with another vendor for shelf life studies?**
No. Our experts can perform these studies – including accelerated aging and real-time aging tests.

**4. Do you have any size limitations on what you can package?**
There are no size limitations – within reason. We can't, unfortunately, package an elephant.

**5. Can you help with package design?**
Absolutely. Our engineers work carefully to design and create packaging that meets user needs, and is as cost-effective as possible. We can often suggest changes to existing packaging designs, too. For instance, when we find that a device can work on a backer card instead of a tray, resulting in a less-expensive and faster process, we'll suggest that.

## RAPID PROTOTYPING MATERIALS
## Are they compatible with EO Sterilization?

By Jim Kasic, Founder and Chairman, Boulder iQ

Rapid prototyping (RP) is, yes, we'll say it, rapidly becoming mainstream in medical device development. Defined as the technique used to quickly fabricate a physical part or assembly, RP generally relies on an additive manufacturing process – commonly known as 3D printing – for manufacture.

Several types of RP exist. While the choice depends on materials, complexity of the part and other factors, the primary types we see among medical device developers are stereolithography and fusion deposition. Stereolithography, the first successful method of 3D printing, is affordable and fast. Fusion deposition, or fused deposition modeling, is a relatively inexpensive, easy-to-use process found in most non-industry 3D printers.

As fantastic as RP is – so much so that some companies are making actual devices (not just prototypes) with it – it bears a number of known disadvantages, ranging from lack of accuracy for some parts to inability to handle certain device features.

*To read about these disadvantages and ways to prevent problems, be sure to read the full article.*

READ FULL ARTICLE

## SUCCESS STORY | Hubly Surgical

**Boulder iQ Helps Hubly Surgical Assemble, Package and Sterilize Advanced Cranial Drill**
Cranial drilling, a widely used technique in neurosurgery, calls for precision of the highest degree in both the process and the equipment. Hubly Surgical, based in Lisle, Illinois, is the developer and manufacturer of the first and only single-use cranial drill with advanced features for efficiency, safety, and use in any medical setting.

Hubly needed help in assembling, packaging and sterilizing its drill, along with validation on the packaged product. As a small start-up company founded in 2019, facing the rigors of testing en route to FDA clearance, Hubly required a partner with expertise and experience, yet was flexible enough to handle unpredictability; variance in batch sizes, and special requests.

*Be sure to read the full article to learn about the successful partnership between Boulder iQ and Hubly Surgical.*

READ FULL ARTICLE

## PAST ARTICLES

Medical Device Packaging Labels 101
*- Med Device Online, March 16, 2022*

Medical Device Packaging Considerations for Product Developers: Begin with the End in Mind
*- Med Device Online, August 11, 2021*

7 Factors to Consider in Selecting a Medical Device Sterilization Contractor
*- Boulder iQ, May 28, 2021*

Quick Turnaround Ethylene Oxide Sterilization | White Paper
*- Boulder Sterilization, September 18, 2020*

Boulder iQ is an expert contract consulting firm providing all the services life sciences companies need to get their products to market as quickly and efficiently as possible. We serve as a single source for device developers, providing full product development and regulatory services under one roof.


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**Areas of Service**
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Product Development
Manufacturing/Packaging
EO Sterilization