DYNACORD

FREQUENT QUESTIONS

1. WHERE DO YOUR EXOSOMES COME FROM?

a. Exosomes are extracted from live, healthy C-Section births.

b. All donors are screened extensively to ensure healthy viable extract can occur.

c. Exosomes come from Wharton's Jelly.

d) Wharton's jelly is derived from umbilical cord tissue and contains many components with remarkable regenerative properties. Studies have shown that Wharton's jelly contains very high concentrations of mesenchymal stem cells (MSCs), which are cells that have the ability to transform into specialized cell types.

When injected into damaged tissues, MSCs may help regenerate damaged tissues and stimulate the strengthening of degenerative cells.

https://hudsonmedical.com/articles/what-is-whartons-jelly/

EXOSOMES FAQ

2. **WHAT TYPE OF FILTRATION IS USED ON YOUR PRODUCTS?**

   a. Tangential Flow Filtration.

3. **WHAT IS THE AGE OF THE PLACENTA YOU USE FOR YOUR HARVEST?**

   a. Placenta is harvested within minutes of the birth and the extraction/culturing of the exosomes begins within hours.

4. **DOES YOUR PRODUCT CONTAIN ANY GENETIC MATERIAL?**

   a. No Dyna Cord exosomes are not stem cells and do not contain any genetic material.

5. IS THE FDA DRUG MASTERFILE AN APPROVAL FROM THE FDA?

a. No the Masterfile is a submission of information regarding the harvesting, manufacturing, storage, and delivery of exosomes. It is the first step in obtaining FDA approval. NOTE: NO Exosomes by any company are currently FDA approved however, the FDA Masterfile Acknowledgment (see attached) is the first and most important step in the process of using Exosomes.

b. The next step in traditional FDA approval is to submit and complete and IND (Investigational New Drug Trial) where approved protocols are followed, and results are tracked holistically. (submitted)

c. There are established cases with organizations like Mayo Clinic where therapies or products that obtain an FDA Masterfile that can sell their product for research purposes.

d. It falls under the same category as Botox for example, listed as research purposes but widely accepted and utilized.

6. ARE YOUR EXOSOMES 361 DESIGNATED?

a. No, 361 designation refers to a classification of tissue by the FDA. The key differentiator of a 361 product is that it has to be "minimally manipulated". Our exosomes are extracted, CULTURED and then GROWN using very detailed, tested processes, food cycles and etc.

b. You can read more about 361 designation at: https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/fda-regulation-human-cells-tissues-and-cellular-and-tissue-based-products-hctps-product-list.

7. HOW ARE YOUR PRODUCTS DIFFERENT FROM KIMERA?

a. The biggest difference other than PRODUCT QUALITY , CONSITENCY and our LOWER PRICE is the concentration of our product. Kimera's 2 most popular products contain 5 billion exosomes for 1 ml (5 billion) DILUTED, 5ml of solution or 5ml (15 billion) DILUTED.

b. Dyna Cord solutions are formulated at a 20 billion exosomes per ml solution. There are currently 3 variations of product: 1 ml (20 billion), 2 ml (40 billion), and 5ml (100 billion). OUR PRODUCTS ARE NOT DILUTED.

c. Kimera does not have an FDA Master File. Dyna Cord is the only laboratory with a Master File issued by the FDA.

8. WHAT IS THE MATERIAL TRANSFER AGREEMENT (MTA)?

a. The material transfer agreement is an establishment of admission and acceptance between the lab, distributor and end purchaser of the exosome products. That acknowledging that the products are not FDA approved and should be used for research purposes.

9. WHAT IS THE COA AND WHAT IS IN IT?

a. The Certificate of Analysis is a lab report from a third-party lab who was contracted to test the contents of the Dyna Cord exosome product. In addition to documenting the stability and sterility of the product it also provides a detailed break down of the proteins, cytokines, growth factors, etc. in the product.

b. The COA is important as is demonstrates the labs commitment to creating a consistent product with quality.

10. WHAT IS THE STATUS OF INDS WITH THE FDA?

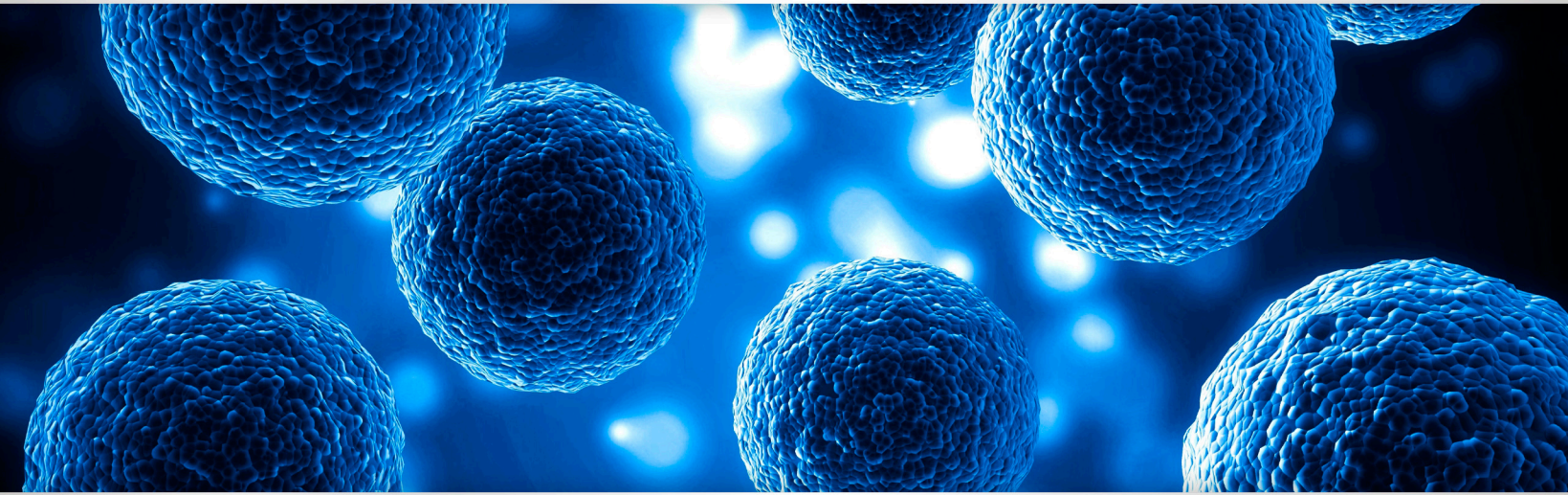
a. There are currently 3 INDs being created by Dyna Cord for its exosome products. They are in the process of being written and re-viewed for submission to the FDA and are anticipated to be underway by Q2 2022.

11. WHY SHOULD I SWITCH TO YOUR PRODUCT?

a. The FDA has not currently approved ANY exosome products for commercial use. This means the entire industry is moving forward at risk as it pertains to FDA approval. In an industry riddled with lawsuits over product consistency and quality, Dyna Cord has prioritized its ability to manufacture and scale a clean, efficacious, safe product every time. If you believe in exosomes and want to know exactly what you are using on your patients, choose a Dyna Cord product.

b. We understand some manufactures have been reprimanded by the FDA for their inconsistency in product as well as multiple lawsuits against them for what has not been in their vials, product manipulation, manipulation of expiration dates and etc. (These are in the public domain, a Google; search will bring up details).

12. WHERE IS THE LAB LOCATED?



a. Dyna Cord is in Baton Rouge, Louisiana.

13. DOES YOUR PRODUCT HAVE AN FDA BLA (BIOLOGICS, LICENSING, APPLICATION)?

a. Currently Dyna Cord has not submitted a license for commercial biologics products. That will come upon completion of an Investigational New Drug Trial and approval of the product which has been submitted.

14. WHAT IS THE STORAGE PROCEDURE FOR EXOSOMES?

a. Exosomes can be stored in a -80 degree freezer for up to 6 months.

b. Exosomes can be stored in a -20 degree freezer (similar to a home freezer) for up to 14 days.

15. HOW ARE YOUR EXOSOMES SHIPPED?

a. Exosomes are packed in dry ice and shipped next day shipping via Fed Ex. Orders submitted before 12:00 noon will be shipped out the same day and should arrive anywhere within the continental US the following day by 10:30 AM. Orders submitted after 12:00 PM will be fulfilled and shipped the following day and will arrive the next following morning.

b. Signature is NOT required upon product delivery; however, it is a Fed Ex policy that a business needs to have someone present for delivery. If a delivery is not successfully completed, the product can be picked up later that evening at the Fed Ex facility or delivered the next morning.

c. The lab does not like to ship after Wednesday because of the high failure rate of delivery acceptance of Friday deliveries. However, exceptions can be made.

d. Failure to accept delivery of the product will be the fault of the customer.

16. IS THE LAB FDA APPROVED?

A

There is not currently an FDA approval for biologics lab like Dyna Cord. However, the FDA Master File is the first of its kind in the industry.

B

Some labs may have a tissue bank certification, but that is only relevant for 361 designations.

17. CAN EXOSOMES BE THAWED AND THEN REFROZEN?

a. Officially, the answer is no. However, there is lab data supporting the fact that exosome solution can be thawed and refrozen up to 3 times without significant degradation of product.

b. If a product is being thawed and refrozen for multiple doses (5 ml = 5 doses @ 1ml) the recommendation would be to thaw the 5 ml product one time and distribute the product into 5 separate 1 ml sterile vials. Refreeze the 1 ml vials and use them as needed. This is not an approved lab procedure but widely utilized.

18. DOES THE LAB HAVE A 482 (NOTICE OF INSPECTION) OR 483 (LIST OF OBSERVATIONS) FROM THE FDA?

a. No, upon completion of the Masterfile submission Dyna Cord reached out to the FDA to coordinate a site visit in an attempt to facilitate these documents, but have not received a response yet, however Dyna Cord has continued to reach out and will process upon response.

b. Dyna Cord has conducted multiple facility audits with FDA Consultants that specialize in regulation and compliance and are competent in the guidelines and regulations.