PURmarrow360[™] Optimal Recovery of Mesenchymal Stem Cells **PRODUCT CHARACTERIZATION**



www.alliantbiotech.com

Title



Bone Marrow MSCs: introduction

Mesenchymal stem cells (MSCs) are a class of adult progenitor cells that can differentiate into various mesenchymal lineages. They are normally isolated from bone marrow (BM) tissue. MSCs can help repair and regenerate a variety of mesenchymal tissues such as bone, cartilage, muscle, and bone marrow stroma. These cells produce growth factors and cytokines that can help repair human tissues^[1].



Preclinical and clinical studies show that the main mechanism underlying the therapeutic benefits is related to paracrine effects such as the facilitation of angiogenesis, the prevention of apoptosis, the suppression of inflammation and the modulation of extracellular matrix dynamics. When tissues or cells have been damaged, the MSCs activate or suppress the immune system to control the entire tissue regeneration process. This is because mesenchymal cells can regulate IS components such as macrophages and neutrophils^[2].

METHODS:

Friedenstein et al. ^[3] were the first to isolate MSCs from bone marrow. Friedenstein's method is currently a standard protocol for the isolation of BM-MSCs. The highest concentration of MSCs obtained from bone marrow aspirate is found in the posterior iliac crest ^[5]. Sampling more than 1 ml of bone marrow from a single site reduces the quality of the aspirate: to increase the proportion of MSCs, many studies concentrate on the bone marrow aspirate (BMA) by centrifugation, thus forming bone marrow concentrate (BMC)^[4].

The main disadvantages of using a centrifuge are:

- A total processing time, including suction, of about 20 minutes
- · Centrifugation is carried out outside the sterile field
- Substantial aspiration of peripheral blood, resulting in a significant reduction In connective tissue, progenitor cell counts ^{[6][7]}
- separation by density gradient centrifugation cannot distinguish between nucleated cells in the peripheral blood (which contain very few stem/progenitor cells) and progenitor cells in the bone marrow^[6]
- centrifugation involves additional handling steps and increases the possibility of contamination^[8]
- up to 40% of mesenchymal stem cells may die because of the spinning
- requires significantly more aspirate (around 10 times more compared to the PUR Marrow 360 device).

Another important aspect concerns the device used to harvest the bone marrow: conventional trocars aspirate from the distal tip of the device, and have several disadvantages:

- involve the sampling of a greater volume from a single site, or sampling from multiple angles, which increases patient morbidity
- cause excess peripheral blood contamination
- diminish cellular yield
- require additional manipulation steps (centrifugation required)
- the cannula retraction causes spongious bone channels breakage
- only a limited number of cells MSCs stay in the spongious marrow trabeculae
- trocar with both open distal tip and side holes are not efficient since peripheral blood has got a significantly lower viscosity than bone marrow and syringe pressure doesn't help the marrow collection from side holes.





PURmarrow360[™] innovative device

PURmarrow360[™] is a state-of-the-art technology designed to selectively aspirate mesenchymal stem cells (MSCs) from the hematopoietic bone marrow, with minimal contamination of sinusoidal peripheral

blood. This is due to an innovative, micrometric myeloaspiration system that uses nozzles positioned along the entire circumference of the Trocar, which is closed at the distal end. The structure of this device means that, once it has got passed the medullary cortex and joints in the bone marrow, it is possible to sample greater medullary cellularity in the same aspirated volume than with similar devices, since the arrangement of the suction holes prevents the sampling of peripheral blood and only samples medullary blood.

PURmarrow360[™] offers a one-step procedure by enabling the simultaneous collection of small samples taken from multiple sites in the bone marrow, thus preserving the structure of the marrow itself and minimising peripheral blood sampling, meaning that higher concentrations of mesenchymal progenitor cells can be obtained ^[8].

PURmarrow360[™] is a single-use device that does not require a centrifuge for the selective harvesting of mesenchymal cells from the bone marrow. Due to the micrometric system for lateral aspiration and the closed distal tip of the Trocar, cellular yield is optimised and peripheral blood contamination is minimised.

During the sampling process, the suction cannula gradually withdraws 1 cm with each complete rotation, selectively collecting up to 1 ml of mesenchymal cells only, from the lateral holes. The micrometric ferrule and the mechanics of the device enable the precise repositioning of the lateral aspiration ports inside the medullary space. After each 1 to 2 ml sampling, the trocar handle is rotated 360° anticlockwise, which retracts the device by approximately 1 cm from the body, and subsequent extractions are made from these new sites in the medulla. This differs from extractions using a conventional, open-tip needle, which is taken from the same insertion site each time.



MAIN FEATURES:

- ALL-IN-ONE DEVICE
- CENTRIFUGE FREE
- NO PROCESSING TIME: IMMEDIATELY READY TO USE
- FASTER AND EASIER PROCEDURE
- 100% LATERAL ASPIRATION
- CLOSED & SEALED DISTAL TIP
- NO PERIPHERAL BLOOD CONTAMINATION
- HIGH CELLULAR YIELD AND REDUCED QUANTITY OF MARROW ASPIRATE
- MICROMETRIC GEAR FOR A CONTROLLED CANNULA RETRACTION
- POINT OF CARE THERAPY
- MINIMALLY INVASIVE PROCEDURE

Validation test

INTRODUCTION

Validation test utilizing flow cytometry. PURmarrow360[™] is an FDA registered 510K product, bone marrow MSC aspiration kit.

METHODS

Myeloaspirate samples were analysed using a flow cytometric method, and the expression of the MSC markers (see table and FACS image) was specifically quantified.



The bone marrow blood was processed as follows:

- 500ul blood was treated with ACK (Ammonium-Chloride-Potassium) to lysate the red blood cells. After two washes with PBS, the cell pellet was incubated for 15 min at room temperature with the following mix of antibodies: CD45 PB, CD3 Pe Cy7, CD90 APC, CD73 PE, CD105 FITC.
- The combination of these antibodies enables the detection of the stromal component (CD73+, CD90+, CD105+) in the nonhematopoietic portion (CD45-, CD34-) of the marrow blood.
- 200ul blood was instead used as an unstained control.
- After 2 washes in PBS + 2% FBS, the samples were fixed in PBS + 2% PFA and a reading was taken on a flow cytometer (BO Facs Canto) calibrated according to the standard criteria of the OSR Facs facility (Fractal).

RESULTS

- Post-superior iliac crest myeloaspiration procedures were performed on non-hemopathic orthopaedic patients with preserved blood composition.
- The volume of each sample was 2 ml. From an operational point of view, the device is undoubtedly userfriendly, easy and practical to use and safe for the operator, with minimal trauma to the patient.
- The vital and measurable cellularity was >95% of the total, of which ~ 85% were hematopoietic (CD45+). The cytofluorimeter analysis showed that the mesenchymal component constitutes ~0.1% of the cells analysed (see table).

SAMPLE	
Live cells (SSC-A-FSC-A)	98.00%
CD45neg	13,80%
CD73+CD90	0,68%
MSCs (CD90+CD73+CD105)	0,093%





DISCUSSION



MSC CD90+CD73+CD105+ 0,093% of live cells

It should be considered that MSCs constitute a very rare population in the marrow, approximately 0.001-0.1% of mononuclear cells (Li H et al. isolation and characterization of primary bone marrow mesenchymal stromal cells. Ann N Y Acad Sci. 2016). Therefore, the results observed were extremely satisfactory:

MSCs = 0,093% of live cells.

Furthermore, a comparative study shows that the use of selective aspiration devices yields more than twice as many fibroblast colony-forming units (CFU-f) per ml than bone marrow concentrate obtained by centrifugation. The selective aspiration devices also resulted in a significantly lower peripheral blood contamination than the sample obtained by centrifuge and required considerably less preparation time and less aspirate.

Conclusions

The results confirm:

- 1. The device's capability to selectively harvest MSCs with a high percentage of cell viability
- 2. The possibility offered by the arrangement of suction holes, which provides high cellularity with minimum volumes of myeloaspirate, thereby minimising trauma, a definite advantage in both orthopaedics and haematology (e.g. bone marrow explants)
- 3. The safety and ease of use for the operator.

The results obtained suggest that new fenestrated trocars such as the PURmarrow360[™] device may be more effective replacements for conventional bone marrow aspiration devices that rely on centrifuge-based systems.

Conventional technologies typically result in the disposal of 35-65% of the cells and growth factors when reduced in centrifuge-based systems during separation from the supernatant^[9]. These cells and growth factors are not removed by the PURmarrow360[™] device: the biological material produced by the device does not require handling steps outside the sterile field, and the entire sample can be used.

Centrifuge-based systems require the bone marrow aspirate to be removed from the sterile field for centrifugation. The final product then re-enters the sterile field following centrifugation and

withdrawal of the product. The option of keeping the product in a sterile field reduces the risk of infection for the patient undergoing the procedure.

From an operational point of view, the device was found to be intuitive, easy and practical to use, safe for the practitioner and minimally traumatic for the patient^[10]. The design automatically repositions the suction cannula and aspirates from the side ports over a wider geography of the bone marrow space, such that consecutive 1ml aspirations can be performed.

This innovative device also minimises peripheral blood contamination. This also suggests that the PURmarrow360[™] device could provide even better results than BMAC alternatives as healthcare practitioners gradually become more familiar with and proficient in using the device.

References:

- 1. Pfitzinger, Mark F. "Mesenchymal stem cells from adult bone marrow." Mesenchymal Stem Cells. Humana Press, 2008. 27-44.
- Jiang, Wei, and Jianyong Xu. "Immune modulation by mesenchymal stem cells." Cell proliferation 53.1 (2020): e12712.
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- hematopoietic organs." Experimental hematology 4.5 (1976): 267.
 4. Wells, Kristina, et al. "Cellular and clinical analyses of autologous bone marrow aspirate injectate for knee osteoarthritis: a pilot study." PM&R (2020).
- Hyer, Christopher F., et al. "Quantitative assessment of the yield of osteoblastic connective tissue progenitors in bone marrow aspirate from the iliac crest, tibia, and calcaneus." JBJS 95.14 (2013): 1312-1316.
- 6. Scarpone, Michael, et al. "Isolation of clinically relevant concentrations of bone marrow mesenchymal stem cells without centrifugation." Journal of Translational Medicine 17.1 (2019): 10.
- 7. Bianco, Sabatino. "Novel Lateral Aspiration Device Compared to Standard Cannula Needle."
- 8. Varady, Nathan H., et al. "Positive early clinical outcomes of bone marrow aspirate concentrate for osteoarthritis using a novel fenestrated trocar." The Knee 27.5 (2020): 1627-1634.
- 9. Harrell, David B., O. F. Brt, and Joseph R. Purita. "Novel Technology to Increase Concentrations of Stem and Progenitor Cells in Marrow Aspiration."
- 10. Hongzhe Li, Stefan Scheding "Isolation and characterization of primary bone marrow mesenchymal stromal cells. Ann N.Y. Acad. Sci ISSN 0077-8923

Contact us for further information at orders@alliantbiotech.com



www.Alliantbiotech.com

Part Number

Description

PURmarrow-360

PUR360 BMA Kit

Bone Marrow Aspiration

A bone marrow harvesting system that overcomes the limitations of a traditional bone marrow needle by allowing the user to aspirate in a measured and controlled manner over a large geography inside the marrow space while restricting peripheral blood infiltration.

This system is composed of a fenestrated cannula and an internal stylet. The rotating spacer mounted on a threated insert allows relative movement of the cannula.



Kit Includes:

- All in one system: fenestrated cannula & internal stylet
 - 20ml Syringe

11 Gauge diameter

Designed to optimize collection of Mesenchymal Stem cells



Close-end needle tip to prevent aspiration of excess blood from the entry channel.



Designed to reduce OR time and personnel



11/5/2024

To Whom It May Concern,

This letter serves as formal authorization for Alliant Biotech to represent SLR Medical Consulting in the promotion and sale of our products and services to healthcare professionals. Alliant Biotech is hereby granted the authority to act on behalf of SLR Medical Consulting in matters pertaining to the marketing, promotion, and sales of our offerings within the healthcare industry.

Authorized Actions:

1. Promote and market SLR Medical Consulting's products and services to healthcare professionals.

2. Engage in sales activities, including negotiating and closing deals with healthcare facilities and professionals.

3. Utilize SLR Medical Consulting's marketing materials and brand assets as necessary to perform the above activities.

4. Invoice healthcare facilities for SLR Medical Consulting's products and services and be considered the "vendor of record" in all transactions.

This authorization is valid from November 5, 2024 to November 5, 2026, unless otherwise revoked in writing by SLR Medical Consulting

If you have any questions or require further information, please do not hesitate to contact us at 214-642-8033

Sincerely,

Matt Gonzales

Chief Financial Officer

SLR Medical Consulting.com Dallas, TX 75204 matt@slrmedicalconsulting.com 281-660-7809



January 11, 2021

Biopsybell s.r.l. % Maurizio Pantaleoni Senior Consultant Maytal Doo Kneza Milosa, 79 Belgrade, Serbia 11000 Serbia

Re: K203397

Trade/Device Name: BONE MARROW MSC ASPIRATION KIT Regulation Number: 21 CFR 876.1075 Regulation Name: Gastroenterology-Urology Biopsy Instrument Regulatory Class: Class II Product Code: KNW Dated: November 6, 2020 Received: November 18, 2020

Dear Maurizio Pantaleoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D. Assistant Director DHT4A: Division of General Surgery Devices OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure

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Form W-9
(Rev. March 2024)
Department of the Treasury Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Give form to the requester. Do not send to the IRS.

Go to www.irs.gov/FormW9 for instructions and the latest information.

Befor	e you begin. For guidance related to the purpose of Form W-9, see Purpose of Form, below.		
	 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line entity's name on line 2.) Alliant Biotech LLC 	1, and enter the business/disregarded	
Print or type. pecific Instructions on page 3.	2 Business name/disregarded entity name, if different from above.		
	3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only one of the following seven boxes. □ Individual/sole proprietor □ C corporation □ S corporation □ Partnership □ Trust/estate □ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership)	Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3): Exempt payee code (if any) Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any) (Applies to accounts maintained outside the United States.)	
See	5 Address (number, street, and apt. or suite no.). See instructions. Requester's name a	and address (optional)	
	6 City, state, and ZIP code		
	Grand Rapids, MI 49505		
	7 List account number(s) here (optional)		
Par	t I Taxpayer Identification Number (TIN)		
Enter	your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid	curity number	
backu	p withholding. For individuals, this is generally your social security number (SSN). However, for a		

resident alien, sole proprietor, or disregarded entity, see the instructions	for Part I, later. For other	
entities, it is your employer identification number (EIN). If you do not have	a number, see How to get a or	
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Note: If the account is in more than one name, see the instructions for lin	e 1 See also What Name and	ï

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Note: If the account is in more than one name, see the instructions for line 1. See also What Name an Number To Give the Requester for guidelines on whose number to enter.

Part II Certification

Under penalties of perjury, I certify that:

- 1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
- 2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
- 3. I am a U.S. citizen or other U.S. person (defined below); and
- 4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here	Signature of U.S. person	Noex 100
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

Date	3	5	24	L
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New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they



Alliant Biotech 2140 Oak Industrial Drive, NE Grand Rapids, MI 49505

888-307-1144

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New Customer Set-up Form

Customer #:			To be assigned by Alliant Biotech
Customer:			
Ship to address:			
City:		State:	Zip:
Bill to address:			
City:		State:	Zip:
Hospital System:			
Accounts Payable Phone #:			
Accounts Payable Email:			
Purchasing Contact :			
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