



All India Institute of Medical Sciences, Bhubaneswar
At - Sijua (Patrapada), Post - Dumuduma, Bhubaneswar (Odisha) - 751 019

To be uploaded in Website: www.aiimsbhubaneswar.edu.in (Tender)

Reference No: J-11077(008)/2019-20/S&P

Dated: 01 Jan 2020

Sub: Procurement of Table Top Platelet Rich Plasma along with 50(Fifty) PRP Kits (Make: Terumo BCT, Model- SMP-2)) for the Department of PMR(Extra Mural Project) at AIIMS, BBSR on Proprietary basis - **Inviting Comments thereon.**

The Department of PMR(Extra Mural Project) of AIIMS, Bhubaneswar has requested for Procurement of Table Top Platelet Rich Plasma (Make: Terumo BCT) from **M/s Terumo BCT INC, USA** through their Indian Subsidiary **M/s Terumo Penpol Private Limited, Kolkata.**

The Notice is being uploaded for general information of prospective manufacturer/Authorized Distributor/Dealers to submit their objection/proposal/comments, if any, on proprietorship of the item.

In case the product of any manufacturer/Authorized distributor/Dealer conforms to the enclosed specifications, they may submit their proposal for the supply of the same along with the brochures, point by point compliance of the enclosed specifications along with all documentary evidence. One quotation of the product may also be submitted.

The objections/comments/proposal should be sent in sealed cover to the Office of Sr. Procurement Cum Stores Officer, AIIMS, Bhubaneswar (Odisha) – 751019 or through E-mail to spo@aiimsbhubaneswar.edu.in, aso.rnpattnaik@aiimsbhubaneswar.edu.in, so as to reach on or before **date: 15-01-2020** failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The ref. no. – **J-11077(008)/2019-20/S&P** dt: 01-01-2020, due on dated: 15-01-2020 should be superscripted on sealed envelope.

Enclosure:

1. Proprietary Article Certificate along with Technical specification from Indenting Officer of Department of PMR(Extra Mural Project), AIIMS, Bhubaneswar. **Annexure-I & II**
2. PAC of M/s. **Terumo BCT INC, USA. Annexure-III**
3. Brochure - **Annexure-IV**
4. Price Quotation of Table Top Platelet Rich Plasma along with 50(Fifty) PRP Kits - **Annexure-V**

Copy to:

- | | |
|--|------------------------------|
| 1. Indenting Officer, Department of PMR(Dr. Apurva Burman) : | for information please |
| 2. Accounts Officer : | for information please |
| 3. IT Cell : | for hoisting in the website. |


Sr. Procurement-cum-Stores Officer


01/01/2020

AIIMS, BHUBANESWAR

Proprietary Article Certificate
Valid for the Current Financial Year

File No. and Date Reference :		
1	Description of article	Table Top Platelet Rich Plasma Machine : -The machine will provide highly concentrated platelet rich plasma (>4 times) and must have options of producing at least 3 biologics (autologous platelet concentrate, bone marrow aspirate concentrate and adiprep) in same machine. - Provided with either or both fixed angle and/or swinging rotors. - It should of benchtop model, containing self-calibrating floating shelf for concentrating bone marrow aspiration. - Dimension of the PRP machine will be around 400 X 500 X 300 (H) mm. - Weight of the machine will be around 30 kg. - The speed of machine should be having rpm of around 4,000 rpm. - It will provide maximum force around 2900xg, maximum capacity will be around 200 ml (minimum 4 tubes capacity) - Microprocessor controls on all run parameters (RPM/RCF, Acceleration, deceleration, time & temperature) for consistent high platelet Yields. - Centrifuge machine will show numeric display, timer etc. There will be LCD display to select parameter. - Power supply of the machine will be around 110-220 V, 50-60 Hz, fitted with Indian plug and sockets. - Capable of operating continuously in ambient temperature of 10-400C and relative humidity of 15-90%. -The PRP machine must be provided with minimum 50 PRP Kits. - Should have audio-visual alarm for error due to imbalance. - Should be having noiseless operation, automatic/manual lid opening and closure. - Should be approved by ISO and BIS/CE/FDA and provide certificate for the same. - Should provide on-site demonstration up to user satisfaction.
2	Forecast of quantity /annual requirement	Only 1
3	Approximate estimated value for above quantity	Approximate Rs. 7,25,000/-
4	Maker's name and address	Terumo BCT. Inc. 10811 West Collins Ave, Lakewood, Colorado USA
5	Name(s) of authorized dealers/ stockists	TERUMO PENPOL Private Limited, I-2, Jawahar Nagar, Kowdiar P O, Thiruvananthapuram - 695003 Mobile: 9378015508
6	I approve the above purchase on PAC basis and certify that : - Note- Tick to retain only one out of (b), C-1) or (c-2) whichever is applicable and cross out others. Please do confirm (a) by ticking it - without which PAC certificate will be invalid.	
6(a)	This is the only firm who is manufacturing / stocking this item. AND	
6(b)	A Similar article is not manufactured / sold by any other firm, which could be used in lieu OR	☒ YES
6(c-1)	No other make/brand will be suitable for following tangible reasons (like OEM/ Warranty, spares.): OR <u>① one machine has option of producing atleast 3 biologics (PRP/BMAC & Adiprep) in same machine</u> <u>② Bench top model, containing self-calibrating floating shelf for concentrating bone marrow aspiration.</u>	☒ YES
6(c)	No other make/brand will be suitable for following intangible reasons (if PAC was also given in the last procurement cycle, please also bring out efforts made since then to locate more sources) : OR	☒ YES - Confirmed
7	Reference of concurrence of finance wing to the proposal :	
History of PAC Purchase of this item for past three years may be given below :		First time purchase
Name of the Supplier		

AIIMS, BHUBANESWAR

Order/ Tender Reference & Date	Quantity Ordered	Basic Rate on Order (Rs.)	Adverse Performance Reported if Any
First time Procurement	First time Procurement	First time Procurement	First time Procurement

Signature of the Indenting Officer

Signature of Approving Authority.....

Date..... Designation of Officer.....

Dr. Apurba Barman
Dr. Apurba Barman, M.D.
Associate Professor
Department of PMR
AIIMS, Bhubaneswar-751019

Specification of Table Top Platelet- Rich Plasma Machine

1. The machine will provide highly concentrated platelet rich plasma (>4 times) and must have options of producing at least 3 biologics (autologous platelet concentrate, bone marrow aspirate concentrate and adiprep) in same machine.
2. Provided with either or both fixed angle and/or swinging rotors.
3. It should of benchtop model, containing self-calibrating floating shelf for concentrating bone marrow aspiration.
4. Dimension of the PRP machine will be around 400 X 500 X 300 (H) mm.
5. Weight of the machine will be around 30 kg.
6. The speed of machine should be having rpm of around 4,000 rpm.
7. It will provide maximum force around 2900xg, maximum capacity will be around 200 ml (minimum 4 tubes capacity)
8. Microprocessor controls on all run parameters (RPM/RCF, Acceleration, deceleration, time & temperature) for consistent high platelet Yields.
9. Centrifuge machine will show numeric display, timer etc. There will be LCD display to select parameter.
10. Power supply of the machine will be around 110-220 V, 50-60 Hz, fitted with Indian plug and sockets.
11. Capable of operating continuously in ambient temperature of 10-40°C and relative humidity of 15-90%.
12. The PRP machine must be provided with minimum 50 PRP Kits.
13. Should have audio-visual alarm for error due to imbalance.
14. Should be having noiseless operation, automatic/manual lid opening and closure.
15. Should be approved by ISO and BIS/CE/FDA and provide certificate for the same.
16. Should provide on-site demonstration up to user satisfaction.

Crus2
Apurba Barman
Dr. Apurba Barman, MD, DNB (PMR)
Associate Professor
Department of PMR
AIIMS, Bhubaneswar-751019

TERUMOBCT

November 05, 2019

PROPRIETARY CERTIFICATE

TO WHOM IT MAY CONCERN

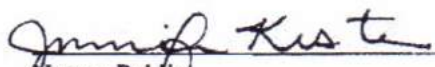
This is to certify that the consumables and disposables for Harvest are manufactured by Terumo BCT and are specific to the equipment and are proprietary in nature.

The items include:

	Harvest
1	SMARTPREP 2
2	SMARTPREP 3
3	Autologous Platelet Concentrate Procedure Pack
4	Bone Marrow Aspirate Concentrate Procedure Pack
5	AdiPrep Procedure Pack
6	Dual Liquid Applicator Kit
7	Spray Applicator Kit
8	Graft Delivery Pack
9	Clear PRP Kit


 Ashley Davis
 Sr. Specialist, Regulatory Affairs

Subscribed and sworn to before me this 5th day of November 2019, in the County of Jefferson, State of Colorado, United States of America.


 Notary Public

Seal

JENNIFER KESTER
 NOTARY PUBLIC
 STATE OF COLORADO
 NOTARY ID # 20044014824
 My Commission Expires 05-01-2020



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HARVEST® PLATELET CONCENTRATE SYSTEM

THE HIGHEST PLATELET CONCENTRATION
WHEN COMPARED TO 12 OTHER SYSTEMS*



Dr. Apurba Barman
Apurba Barman, MD, DNB (PMR)
Associate Professor
Department of PMR
Rajdurg, Bhubaneswar-751019

HARVESTING PLATELET-RICH PLASMA

Platelet-rich plasma (PRP) is a blood product with a concentration of platelets greater than the baseline level.¹ Autologous PRP also contains growth factors that may help optimize the conditions needed for the healing of bone and soft tissue.^{2,3}

The Harvest platelet concentrate system is designed for the safe and rapid preparation of highly concentrated autologous PRP. The PRP can be mixed with autograft and allograft bone before application to an orthopedic surgical site.

While platelets are the primary component of PRP, preparations also contain other cellular components such as white blood cells (WBCs) and peripheral stem cells. These key components play a biological role in the healing process. Platelets are rich in growth factors which support several key processes, including stem cell recruitment, angiogenesis, cell proliferation and differentiation.⁴ When more platelets are isolated in a PRP preparation, more growth factors can be delivered to the application site.

Growth factor concentration is directly proportional to platelet concentration.⁵ PRP produced using the Harvest SmartPrep® Multicellular Processing System delivers the highest concentration and yield of platelets when compared to 12 other systems.*

*Compare the numbers. Find the mean nucleated cell count and yield for the 12 other systems at HARVESTTECH.COM/clinician.^{6,7,8,9}

QUALITY: NEVER COMPROMISE

The Harvest SmartPrep system has the ability to generate up to 1.5 million platelets/ μ L of PRP. Some other systems do not produce high enough platelet concentrations to facilitate angiogenesis—a biological process critical to healing.¹

The Harvest platelet concentrate system contains essential components to generate PRP, including:^{4,10,11,12}

- Platelet concentration at 5 to 6 times baseline levels^{4,10,12}
- Significantly elevated levels of all key growth factors critical to the healing process^{4,10,12}
- Retention of the stem-cell-rich mononuclear WBC fraction (as evidenced by CD34+ counts)
- Reduced levels of the inflammatory granulocyte WBC fraction¹⁴

FLEXIBILITY: EXPANDED TREATMENT OPTIONS

The SmartPrep system has 510(k) clearance to process all three major biologics, including PRP, concentrated bone marrow aspirate (BMA) and concentrated adipose tissue.^{10,14}

The SmartPrep System is a single platform that enables you to offer multiple treatment options to patients.

Processes All Three Autologous Biologics

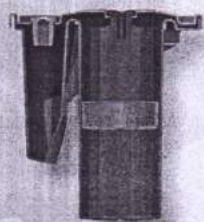


Harvest® Platelet
Concentrate System

Harvest® Bone Marrow
Aspirate Concentrate
(BMAC®) System

Harvest®
AdiPrep® Adipose
Concentration System

Cur
Dr. Apurba Barmati, M.D., M.Sc., M.P.H.
Associate Professor
Department of PMR
AIIMS, New Delhi-110029-751019



The Harvest PC process disposable includes a proprietary, self-calibrating floating shelf that is optimized for concentrating platelets. The floating shelf is engineered to concentrate

60 mL of starting product from a healthy patient with a normal baseline platelet count into as many as 1.5 million platelets/ μ L in 10 mL.^{4,12,13,16}

Selective Capture of the Stem-Cell-Rich Mononuclear White Blood Cell (WBC) Fraction

The floating shelf used in the Harvest PC process disposable is designed to selectively capture the mononuclear cell fraction of the WBC population, unlike many other PRP systems that remove this important component. This mononuclear cell fraction contains the majority of peripheral stem cells, identified by the CD34+ marker. CD34+ cells aid in angiogenesis and tissue regeneration at the application site.^{2,3} The concentration of stem cells found in PRP prepared on the SmartPrep system is indicated by the predominance of CD34+ cells.⁸

Selective Reduction of the Inflammatory Granulocyte Fraction

Similarly, the floating shelf of the Harvest PC process disposable also preferentially reduces the granulocyte population in the final PRP product, delivering lower-than-baseline levels to limit inflammation. This chart shows the composition and concentration of a typical PRP preparation from the Harvest platelet concentrate system:

Composition of PRP When Prepared on the SmartPrep System

	Whole Blood	PRP on SmartPrep System
WBCs	$5.83 \times 10^3/\mu\text{L}$	$21.09 \times 10^3/\mu\text{L}$
Mononuclear cells	34.78%	75.54%
Granulocytes	65.22%	24.46%
CD34+ (total cells delivered)		171,571

Kevy S., et al. Defining the composition and healing effect of platelet-rich plasma for regenerative medicine. Poster: TERMIS-Americas; December 5-8, 2010; Orlando, Florida.

RELIABILITY: PROVEN RESULTS

In addition to generating concentrated autologous biologics in as little as 15 minutes' processing time,¹⁶ the Harvest technology also provides clinicians and physicians with the following advantages:

- Generates biologic treatments with no manual adjustment from patient to patient
- Produces concentrated, high-quality, injection-ready biologics with simple operation
- Delivers low run-to-run variability^{10,11,16}

Automated Processing

Combined with SmartPrep system procedure packs, the SmartPrep system automates the point-of-care processing of biologics.

- Reduces the number of steps versus a manual method
- Simplifies training among multiple users

Designed to Reduce Risk of Contamination

The resealable injection ports on the Harvest PC process disposable can be aseptically disinfected prior to entry. This significantly reduces the risk for contamination of the final product.¹⁷

Delivery Options



Enriched Bone Grafts



Topical Spray (SK/S Shown)



Percutaneous Injection



Liquid Application (LK/2 Shown)

To arrange an evaluation or for more information, call 1.877.8.HARVEST (toll-free) or visit HARVESTTECH.COM.

Harvest Technologies, a Terumo BCT company, has long been a leader in point-of-care cell therapy products.

Harvest Terumo BCT is a global leader in blood component, therapeutic apheresis and cellular technologies, offering more than 30 years of cell processing expertise and a comprehensive range of solutions that cover the continuum of cell therapy—from point-of-care to cell therapy manufacturing.

As a leader in innovation with established global reach, we are shaping the future of cell therapy.

INDICATIONS FOR USE

The Harvest platelet concentrate system is designed to be used for the safe and rapid preparation of autologous PRP from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone before being applied to an orthopedic surgical site as deemed necessary by the clinical use requirements.

RISK INFORMATION

This information does not take the place of discussing your medical condition with your doctor. These procedures require needle access, possibly resulting in apprehension, discomfort, tenderness, bruising, swelling, bleeding or pain at the access site, at which there is a small risk of infection. Lightheadedness, fainting, nausea or vomiting may occur. Before any medical procedure, tell your doctor about prescription and nonprescription medicines and any natural or herbal remedies you are taking or plan to take; and consult your insurance company to verify coverage.

Scientific References

1. Marx RE. Platelet-rich plasma (PRP): What is PRP and what is not PRP? *Implant Dent*. 2001;10(4):225-228.
2. Matsumoto T, et al. Therapeutic potential of vasculogenesis and osteogenesis promoted by peripheral blood CD34-positive cells for functional bone healing. *Am J Pathol*. 2006; 169(4): 1440-1457.
3. Middleton KK, et al. Evaluation of the effects of platelet-rich plasma (PRP) therapy involved in the healing of sports-related soft tissue injuries. *The Iowa Orthopaedic Journal*. 2012; 32: 150-163.
4. Giusti I, Rughetti A, D'Ascenzo S, et al. Identification of an optimal concentration of platelet gel for promoting angiogenesis in human endothelial cells. *Transfusion*. 2009;49(4):771-778.
5. Eppley BL, Woodell JE, Higgins J. Platelet quantification and growth factor analysis from platelet-rich plasma: implications for wound healing. *Plast Reconstr Surg*. 2004;114(6):1502-1508.
6. El-Sharkawy H, Kantarci A, Deady J, et al. Platelet-rich plasma: Growth factors and pro- and anti-inflammatory properties. *J Periodontol*. 2007;78(4):661-669.
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8. Matsumoto T, Mifune Y, Kawamoto A, et al. Fracture induced mobilization and incorporation of bone marrow-derived endothelial progenitor cells for bone healing. *J Cell Physiol*. 2008;215(1):234-242.
9. Mifune Y, Matsumoto T, Kawamoto A, et al. Local delivery of granulocyte colony stimulating factor-mobilized CD34-positive progenitor cells using bioscaffold for modality of unhealing bone fracture. *Stem Cells*. 2008;26(6):1395-1405.
10. Nurden A, Nurden P, Sanchez M, Andia I, Anitua E. Platelets and wound healing. *Front Biosci*. 2008;13(9):3532-3548.
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14. Data on file.
15. Muschler G. Comparison of bone marrow aspiration and bone core biopsy as methods for harvest and assay of human connective tissue progenitor. Paper 41 presented at: 58th Association of Bone and Joint Surgeons Annual Meeting; April 3-7, 2006; Buenos Aires, Argentina.
16. Kevy SV, Jacobson MS. Immune Disease Institute. Platelet-rich plasma preparation: A comparison of the Harvest SmartPreP® 2 APC+® with the Arthrex ACP. 2009. Unpublished data.
17. Center for Blood Research Laboratories. Sterility of platelet concentrates collected with the SmartPreP System and disposables. 2001;TR-063. Unpublished data.

Terumo BCT, Inc.

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TERUMO PENPOL®**TERUMO PENPOL Private Limited**

(Formerly Known as TERUMO PENPOL Limited)

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To,
The Director
All India Institute of Medical Sciences
Bhubaneswar -751019.

Letter No. TPPL/19-20/HM/03

Dated: 14.12.2019

Sub: Price Certificate for Smart Prep2 Machine

Respected Sir,

This is to certify that the price offered does not exceed the price we offer/sell to other organization with identical description along with 50 units of free samples.

Thanking You,
Yours faithfully,
For TERUMO PENPOL Private Limited

SANJOY ROY CHOWDHURY
Regional Manager (East)
Mobile: 9830406866
E-mail: Sanjoy.chowdhury@terumobct.com



[Signature]
Dr. Apurba Barmann, MD, DM (PMR)
Associate Professor
Department of PMR
AIIMS, Bhubaneswar-751019

Registered Office : P.B. No. 6105, I-2, Jawahar Nagar, Thiruvananthapuram - 695 003, Kerala, India

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website : www.terumopenpol.com
Corp. Mail ID : info@terumopenpol.com

To,
The Director
All India Institute of Medical Sciences
Bhubaneswar -751019.

Letter No. TPPL/19-20/HM/03
Dated: 14.12.2019

Sub: Quotation for Harvest Machine

Respected Sir,

We are pleased to offer our proposal for Smart Prep Machine. The quantity and Prices are as indicated hereunder for your kind perusal and consideration.

Description of Goods: Smart Prep2
Make: TERUMO BCT
Model: SMP-2

Unit Price with all accessories in technical specification as stated on next page which includes 50 (fifty) units of free kits	Quantity of machine	Total Price including Tax
Rs.729000.00	1	Rs.729000.00

Warranty: 03 (Three) years from the date of installation of the machine.
Annual Comprehensive Maintenance Contract after expiry of warranty

Name of the Item	1 st Year (Rs.)	2 nd Year (Rs.)	3 rd Year (Rs.)	4 th Year (Rs.)	5 th Year (Rs.)
Smart Prep	24000	26400	29040	31944	31944

Delivery Period: 60 days from the date of Purchase Order.
Payment terms: As per rule of AIIMS, Bhubaneswar.

For, TERUMO PENPOL Private Limited

SANJOY ROY CHOWDHURY
Regional Manager (East)
Mobile: 9830406866
E-mail: sanjoy.chowdhury@terumobct.com



Cm
Dr. Apurba Barman, M.D.(PMR)
Associate Professor
Department of PMR
AIIMS, Bhubaneswar-751019

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