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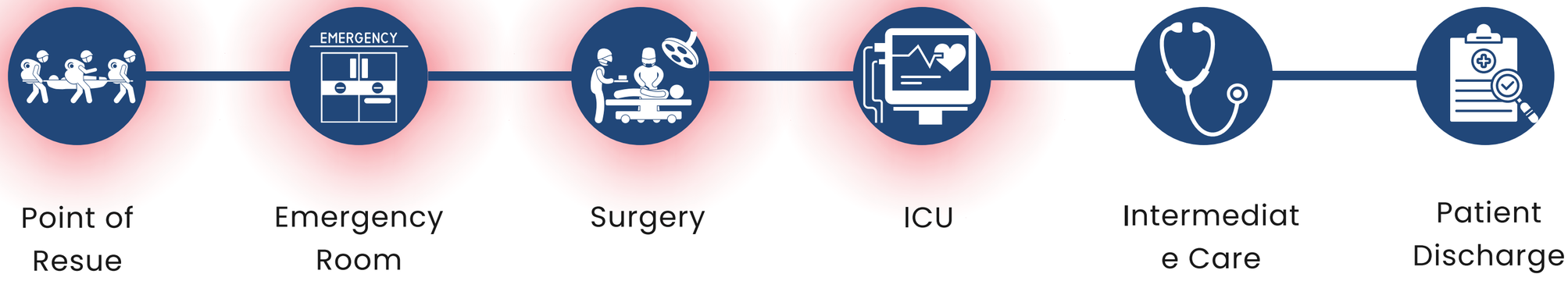
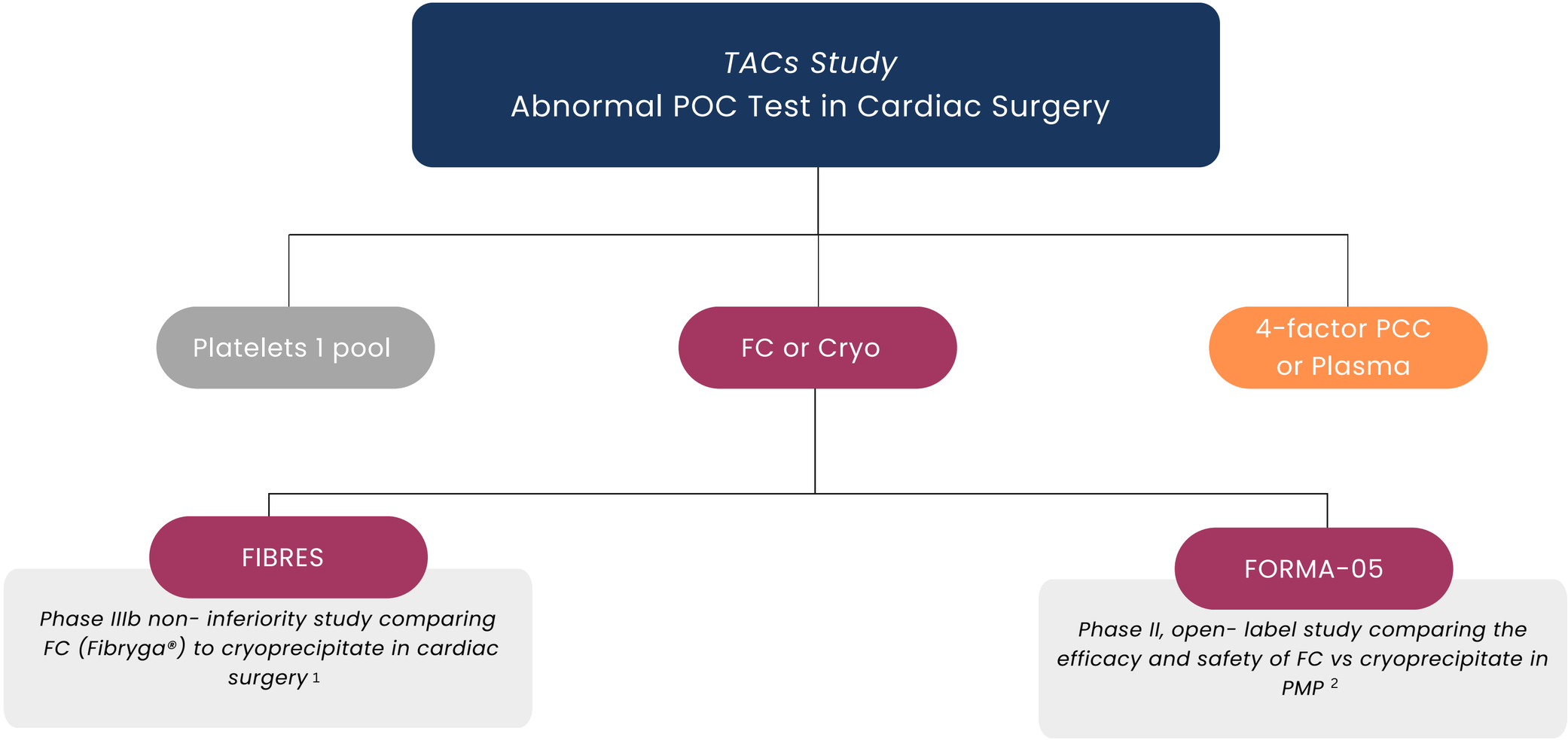
FIBRYGA

The Only Approved Fibrinogen Concentrate for Surgical Procedures

Transformation of transfusion and bleed management



octaplasma® fibryga® octaplex®



1: Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11. 2.
2: Roy A, Stanford S, Nunn S, et al. Efficacy of fibrinogen concentrate in major abdominal surgery – a prospective, randomized, controlled study in cytoreductive surgery for pseudomyxoma peritonei. J Thromb Haemost. 2020;18(2):352-363.

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The Fibryga Clinical Program

The only FC (Fibryga®) in Canada extensively studied in AFD

FORMA-05

Prospective, randomized, controlled, **phase II,** open- label study c**omparing the efficacy and safety of FC vs cryoprecipitate** for bleeding patients undergoing **Pseudomyxoma Peritonei (PMP) cytoreductive surgery** [4]

FIBRES

Phase IIIb non- inferiority study comparing FC (Fibryga®) to cryoprecipitate in cardiac surery [1]

Post hoc analysis

Exploring the clinical interaction between cardiac surgery duration and efficacy of FC and cryoprecipitate in patients from the FIBRES trial[2]

Post hoc analysis

To determine the **cost effectiveness of FC vs. cryoprecipitate** in surgeries from the FIBRES trial[3]

1. Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11.
2. Bartoszko J, Martinez-Perez S, et al; FIBRES Study Investigators. Impact of cardiopulmonary bypass duration on efficacy of fibrinogen replacement with cryoprecipitate compared with fibrinogen concentrate: a post hoc analysis of the Fibrinogen Replenishment in Surgery (FIBRES) randomised controlled trial [published online ahead of print, 2022 Jun 27]. Br J Anaesth. 2022; S0007-0912(22)00251-3.
3. Abrahamyan L, Tomlinson G, et al. Cost-Effectiveness of Fibrinogen Concentrate vs. Cryoprecipitate for Treating Acquired Hypofibrinogenemia in Bleeding Adult Cardiac Surgical Patients. JAMA Surgery. 2022. Accepted for publication.
4. Roy A, Stanford S, et al. Efficacy of fibrinogen concentrate in major abdominal surgery – a prospective, randomized, controlled study in cytoreductive surgery for pseudomyxoma peritonei. J Thromb Haemost. 2020;18(2):352-363.

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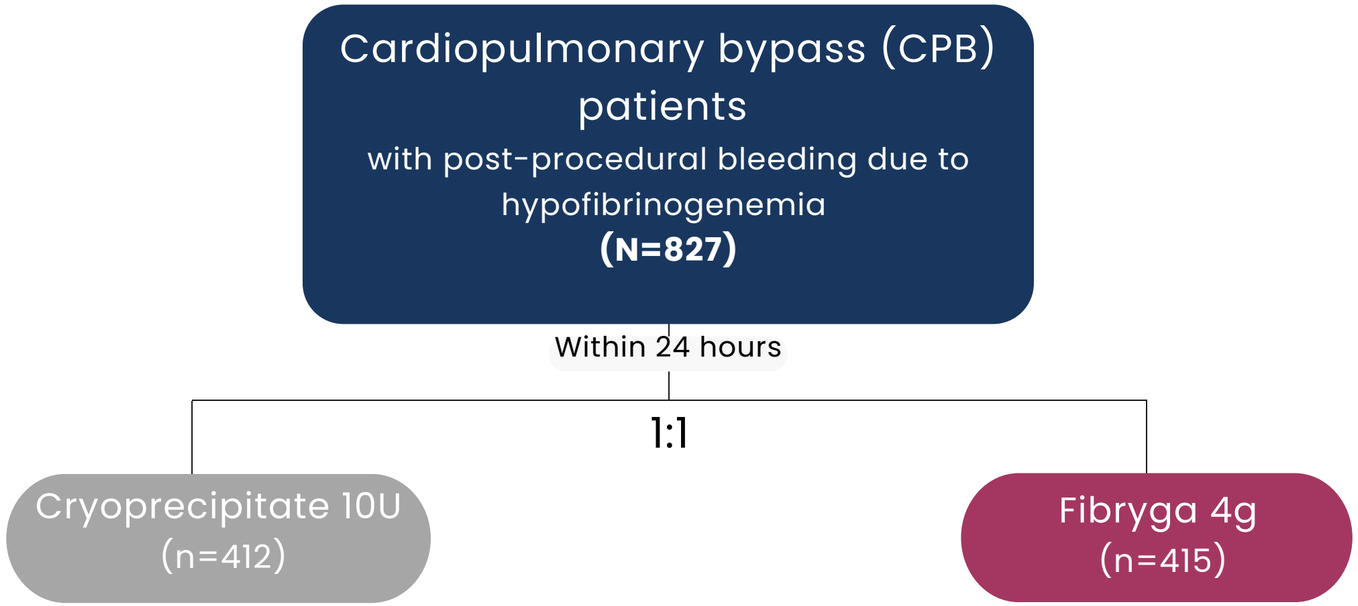
FIBRES: Study Design

Non-inferiority study comparing FC (Fibryga®) to cryoprecipitate in cardiac surgery

Investigator-initiated, single-blinded, multicenter, randomized, phase III trial at 11 centres in Canada



1. Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11.

FIBRES: Study Endpoint

Cardiopulmonary bypass (CPB) patients
with post-procedural bleeding due to hypofibrinogenemia
(N=827)

1:1
10 U Cryo or 4g FC

Primary Endpoint

Cumulative allogeneic blood component units (RBC, platelets, and plasma) administered for 24 hours post-CPB.

Secondary Endpoint

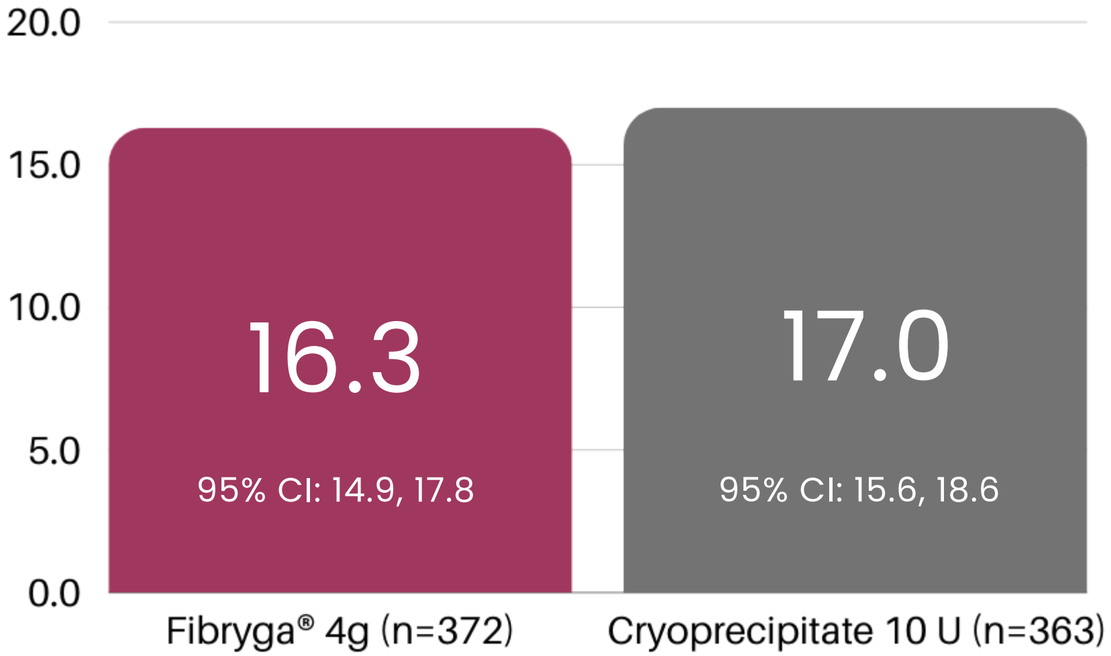
- Individual blood components administered for 24 hours post-CPB
- All transfusions from the beginning of surgery to day 7 post-CPB
- Bleeding severity (UDPB*) for 24 hours post-CPB

1.Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11.

FIBRES: Primary Endpoint Result

Fibryga® was non-inferior to cryoprecipitate for ABP* use in cardiac surgery patients

Cumulative allogenic blood component units
administered for 24 hours post-CPB, mean (95% CI)



Mean ratio 0.96(1-sided 97.5% CI -∞,1.09; p<0.001 for non-inferiority)

*Allogenic blood product

1. Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11.

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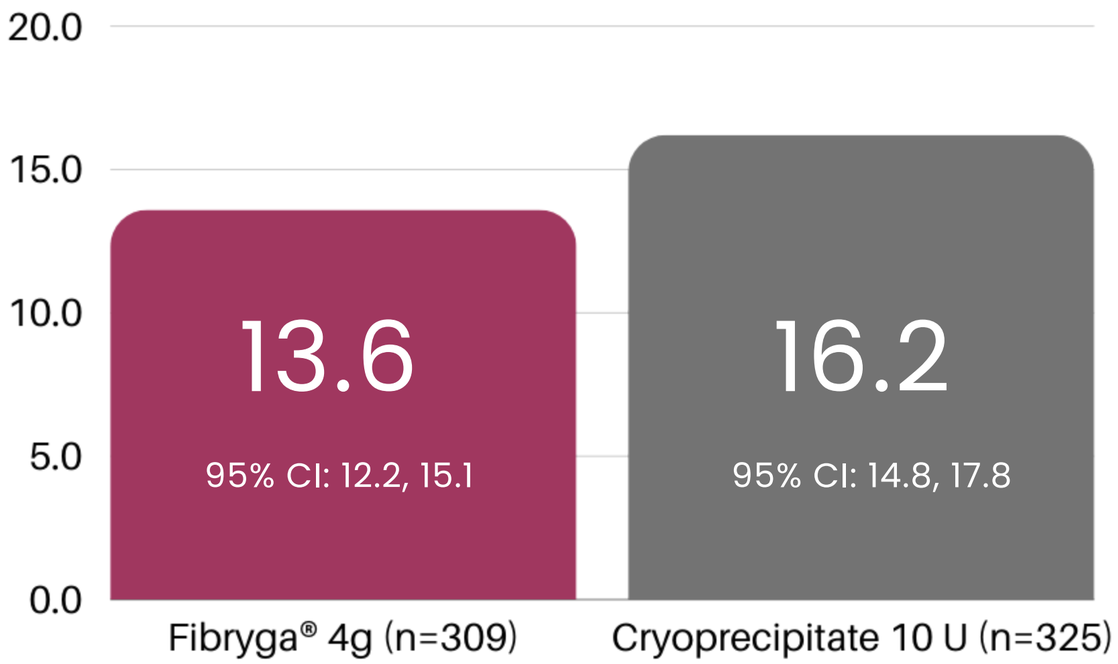
FIBRES: Superior Results in Non-Critical Cardiac Surgery Patients

Fibryga® was superior to cryoprecipitate for ABP* use in non-critical cardiac surgery patients

Cumulative allogenic blood component units
administered for 24 hours post-CPB, mean (95% CI)



Mean ratio 0.84 (1-sided 97.5% CI -∞,0.96; p<0.001)

1. Callum J, Farkouh ME, et al. Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: the FIBRES randomized clinical trial. JAMA. 2019;322(20):1-11.
2. Bartoszko J, Martinez-Perez S, et al; FIBRES Study Investigators. Impact of cardiopulmonary bypass duration on efficacy of fibrinogen replacement with cryoprecipitate compared with fibrinogen concentrate: a post hoc analysis of the Fibrinogen Replenishment in Surgery (FIBRES) randomised controlled trial [published online ahead of print, 2022 Jun 27]. Br J Anaesth. 2022; S0007-0912(22)00251-3.11.

*Allogenic blood product

Fibryga at your Institution:

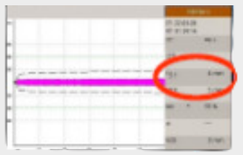
Recommended dosing for Acquired Fibrinogen Deficiency* (AFD)

Initial Dose

4g

Additional Doses

*As needed when plasma Fibrinogen <200 mg/dL or FIBTEM A10 <10mm***



Infusion speed 20 mL/min (max) to deliver 4 g dose in **only 10 minutes**

MHP Order set: Upon initiation call Blood Bank to send

- ☑ 8 units of RBC
- ☑ 4 units of S/D Plasma
- ☑ **4 grams** of Fibryga (1 gram = 1 box)

For additional blood products - Must call for release

- ☐ __ grams of Fibryga

*For dosing in CFD, review the product monograph
**Or equivalent values generated by other thromboelastometry/thromboelastography methods.

1.Fibryga® Product Monograph. Octapharma Canada Inc. October 24, 2024

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Fibryga and Octaplex at your Institution:

Recommended dosing for Acquired Fibrinogen Deficiency* (AFD)

Initial Dose

4g

Initial Dose

2000 IU

Infusion speed 20 mL/min (max) to deliver 4 g dose in **only 10 minutes**

MHP Order set: Upon initiation call Blood Bank to send

- ☑ 4 units of RBC in Pack 1 & 2
- ☑ 4 units of S/D Plasma

MHP Order set: Where plasma not available

- ☑ **2000 IU** of Octaplex
- ☑ **4 grams** of Fibryga (1 gram = 1 box)

*For dosing in CFD, review the product monograph

**Or equivalent values generated by other thromboelastometry/thromboelastography methods.

1.Fibryga® Product Monograph. Octapharma Canada Inc. October 24, 2024

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Fibryga at your Institution:
Designed for ease of use and with end user in mind

Fast reconstitution[1]

<5 minutes to reconstitute using the Nextaro® transfer device*

Flexible Storage[1]

4-year shelf-life at room temperature or refrigerator **2–25°C**

Long stability after reconstitution[1]

24 hours at room temperature - **+25°C**

Cost-savings2,3

Cost effective as compared to cryoprecipitate[2] and **$7.4 million in savings** for Québec[3]**

1. Fibryga® Product Monograph. Octapharma Canada Inc. October 24, 2024.
2. Abrahamyan L, Tomlinson G, et al. Cost-Effectiveness of Fibrinogen Concentrate vs. Cryoprecipitate for Treating Acquired Hypofibrinogenemia in Bleeding Adult Cardiac Surgical Patients. JAMA Surgery. 2022. Accepted for publication.
3. Evaluation of Fibryga (TM) (human fibrinogen concentrate) - acquired fibrinogen deficiency. INESSS. https://www.inesss.qc.ca/en/publications/publications/publication/evaluation-de-fibrygamc-concentre-de-fibrinogene-humain-deficit- acquis-en-fibrinogene.html. Published June 28, 2022.

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NEW

Nextaro: Simplified Workflow with Faster Access in High-Stakes Setting

Faster, More Reliable Reconstitution for Critical Therapies

Streamlining Reconstitution to Ensure Faster, **Error-Free Delivery** of Octaplex and Fibryga from Blood Bank to Bedside

Designed for bedside use, enhancing training effectiveness and minimizing wastage in hospitals

octapharma

NEW

Why Nextaro?

fibryga®
octaplex®
wilate®

Designed to simplify and accelerate the preparation of **Fibryga, Octaplex, and Wilate**—bringing these therapies to patients faster and with greater ease, in settings where every moment counts.

Older Transfer Devices:
Octajet and Mix2Vial

New Transfer Device:
Nextaro

Feature	Octajet	Mix2Vial	Nextaro
Spike Protection	Exposed	Protected	**Fully Protected**
Filtration	Single, separate	Single, Integrated	**Dual, Integrated**
Connection Order	Powder Vial First	Solvent Vial First	**Solvent Vial First**
Flow velocity	Single side spike opening may lead to foam formation		**Two side spike openings reduce foam formation**

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NEW

Nextaro Device: The Preferred Transfer Device for HCPs

Built in filters for both the solvent and the product

Improved grip and handling for safety, ergonomic user-friendly design

Quick reconstitution, under 5 minutes at room temperature

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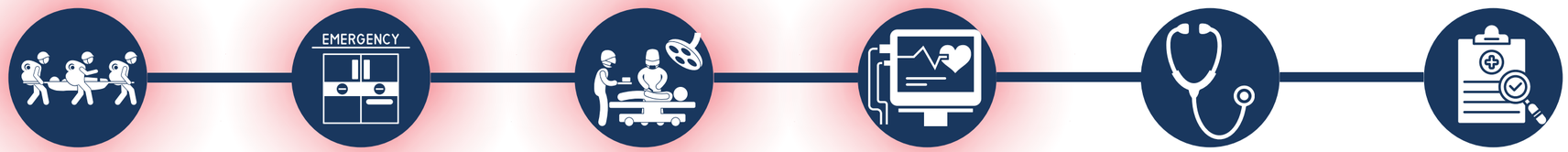
NEW

Nextaro Device: A Care Driven Approach

Faster, More Reliable Reconstitution for Critical Therapies

Consistent across products -
Available for Fibryga, Octaplex and Wilate



Point of Resue

Emergency Room

Surgery

ICU

Intermediat e Care

Patient Discharge

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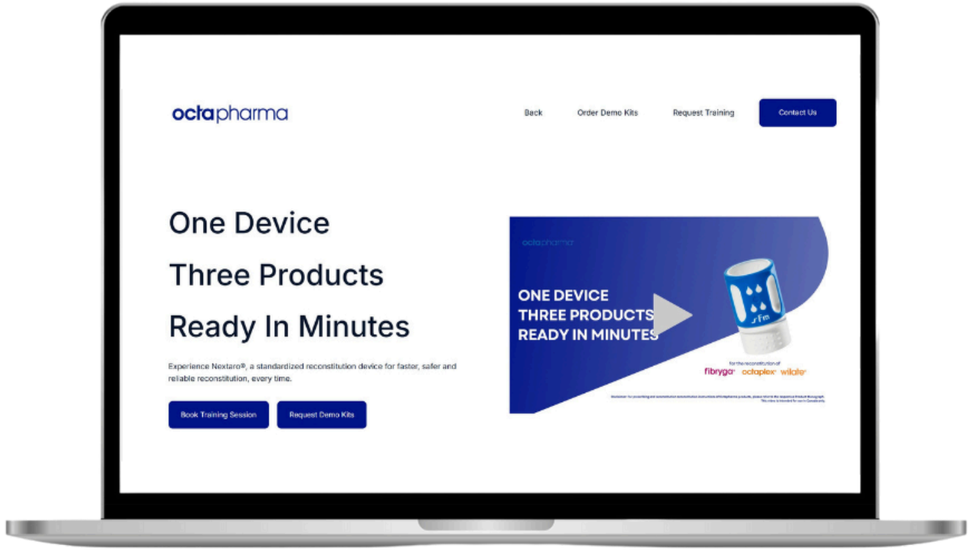
NEW

Supporting This Transition

Fibryga Reconstitution Resources



Nextaro self-service microsite

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CBS letter

Canadian Blood Services BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

INFORMATION ONLY

Fibrinogen concentrate – no restrictions on brand mix

Customer Letter # 2021-29

2021-06-09

Dear Colleagues:

As an update to customer letters 2020-14 and 2020-43, Canadian Blood Services is pleased to announce that supplies of fibrinogen concentrate (Fibryga® manufactured by Octapharma, and RiaStap® manufactured by CSL Behring) are such that customers may now order any brand for their patients.

There are no restrictions on the percentage of each brand that may be ordered.

Customers anticipating large shifts in their brand ordering practices are requested to contact their local Canadian Blood Services site in advance so that appropriate supply arrangements can be made to accommodate these shifts.

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

This customer letter can also be viewed at www.blood.ca in the "Hospitals Services" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,

Sylvain Grenier,
Director, Plasma Protein and Related Products Formulary Program

Canadian Blood Services BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

INFORMATION ONLY

Introduction of Nextaro Reconstitution Device for Octaplex, Fibryga and Wilate

Customer Letter # 2025-11

2025-04-15

Dear Colleagues:

Octapharma Canada has introduced 'Nextaro', the new reconstitution device for Octaplex, Fibryga and Wilate.

Attached is Octapharma's Introductory Letter containing details regarding the reason for the change, the benefits of the new device, timelines and resources.

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

This customer letter can also be viewed at www.blood.ca in the "Hospital Services" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,

Andrea Moore
Director, Planning

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Relevant warnings and precautions:

- *Risk of infectious agents with products made from human plasma.*
- *Risk of allergic reaction.*
- *Patients should be monitored for risk of thrombosis.*
- *Safety has not been established for use in human pregnancy. Benefits and risks to pregnant women should be carefully weighed.*
- *Safety has not been established for use in nursing women. Should be given with caution.*
- *Determination of the patient's fibrinogen level using an appropriate method (e.g., Clauss fibrinogen assay) is recommended before and during the treatment to avoid overdosing or underdosing.*

For more information:
Please consult the product monograph for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this advertisement.

Thank you!