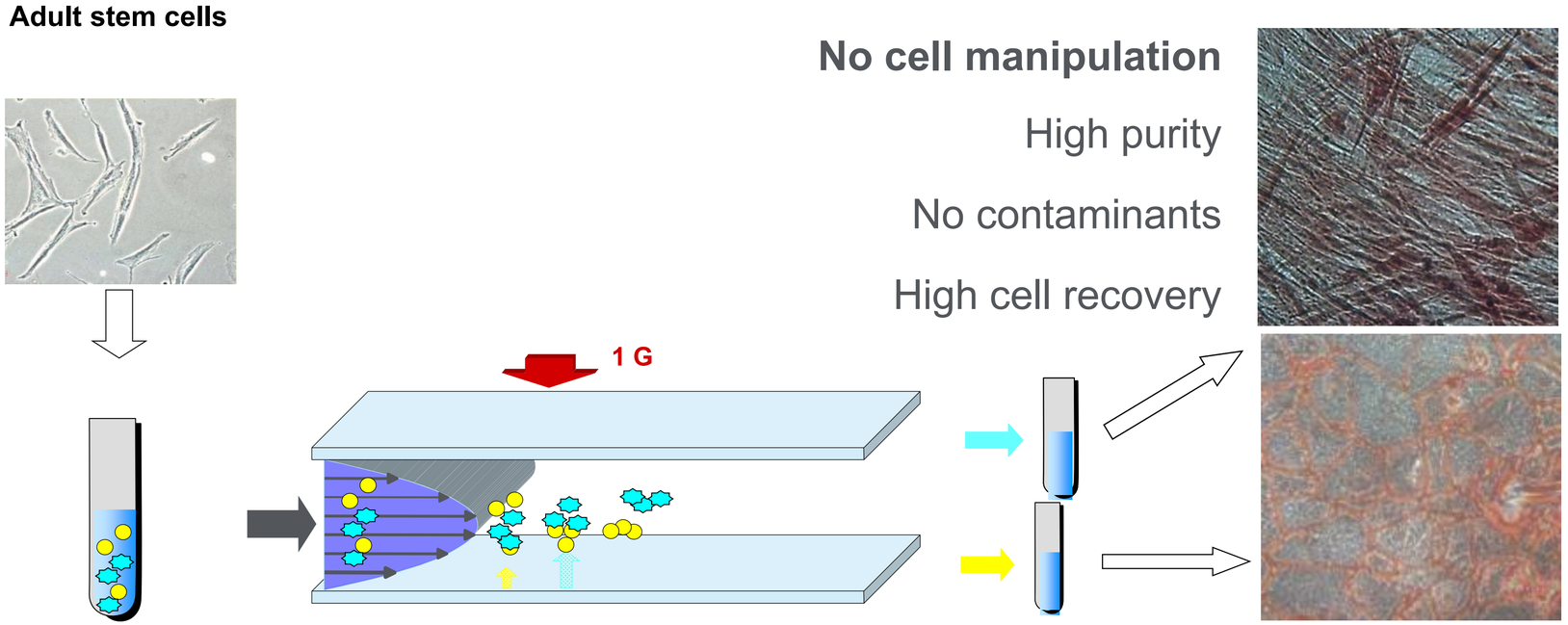
Stem Sel®

your best *cell*ection

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

The research-based IP

"Method and device to fractionate stem cells" (Patented, UniBO)



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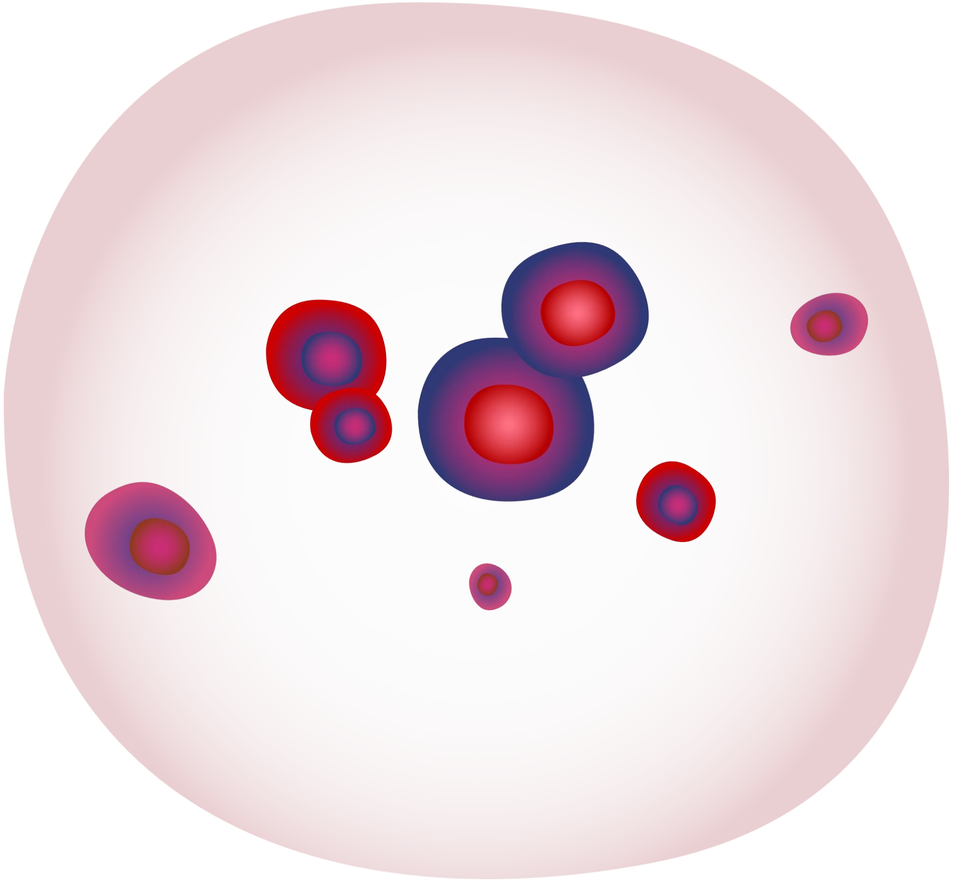
Users need instrumentation, not prototypes!

About

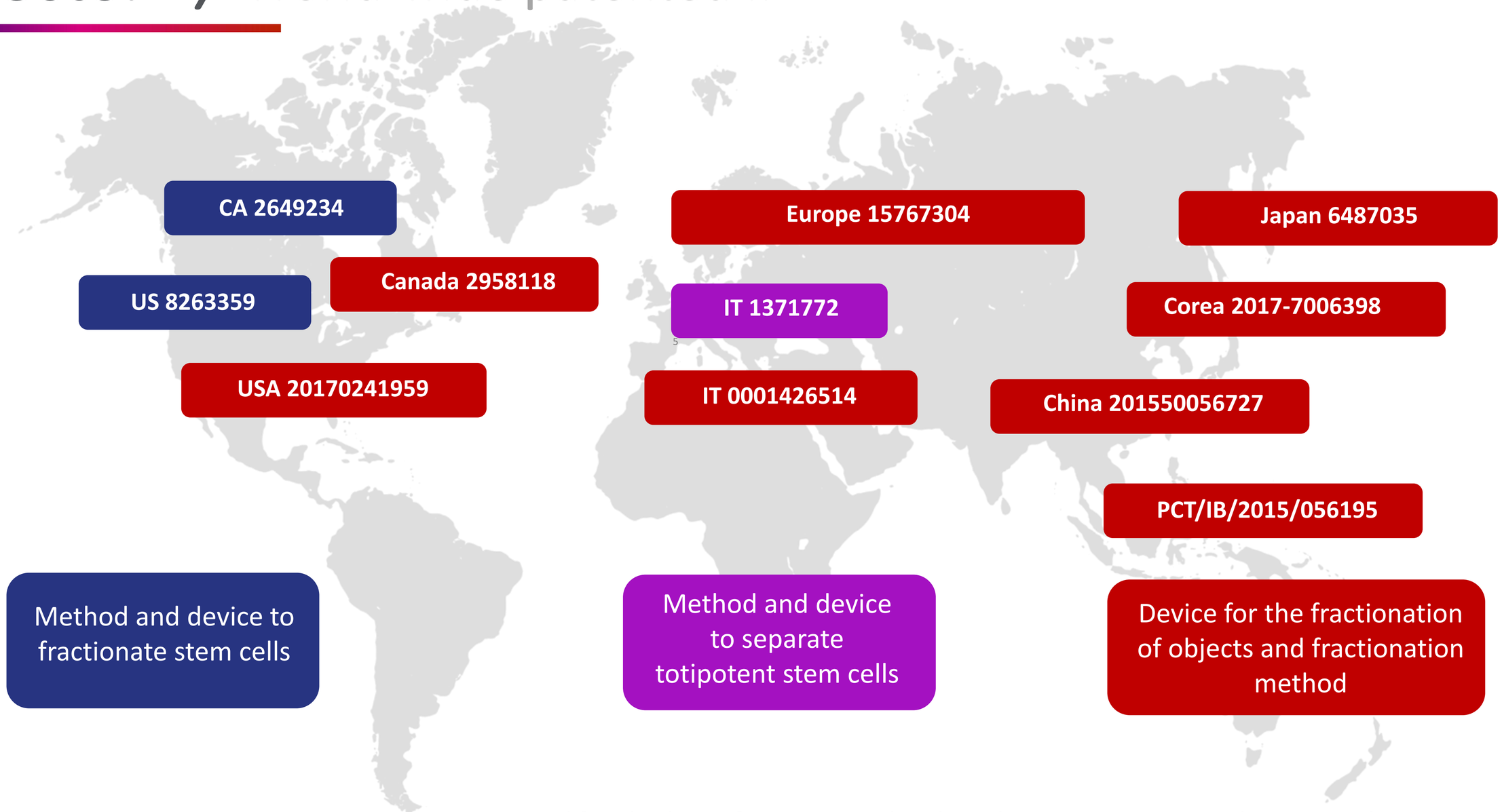
- **Stem Sel Srl** is an innovative PMI founded in 2013 as a **spin-off company from the University of Bologna.** It is participated by the **Academic Team**, **Business Angels**, the incubator **AlmaCube Srl**, the two investment funds **Berrier Capital Srl** (through Start Club S.r.l.) and **O.G.I.I. (LendLease Group),** and by crowdfunding investors. In 2024, it was financed by **CDP «Rilancio Start-Up»** through a "convertible equity instrument" (SFP).



- **Mission** is R&D, industrial engineering, and commercialization of an instrument, based on an **innovative technology,** with the goal to become the **gold standard for non-invasive selection, counting and characterization of cells for ATMPs.**

- Therefore, Stem Sel Srl has developed **Celector®**, based on a **worldwide proprietary technology and device. Chromatography** is one of the **most used techniques for QC** of molecules and nanoparticles, used as drugs, but of course it **can not be applied** to **living cells: Celector® is the *cell chromatograph.***

Celector® / World-wide patented IP



CA 2649234

US 8263359

Canada 2958118

USA 20170241959

Method and device to fractionate stem cells

Europe 15767304

IT 1371772

IT 0001426514

Method and device to separate totipotent stem cells

Japan 6487035

Corea 2017-7006398

China 201550056727

PCT/IB/2015/056195

Device for the fractionation of objects and fractionation method

Celector® / Patented device

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International Bureau

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WIPO | PCT

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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Published:

— *with international search report (Art. 21(3))*

WO 2016/027204 A1

(54) Title: DEVICE FOR THE FRACTIONATION OF OBJECTS AND FRACTIONATION METHOD

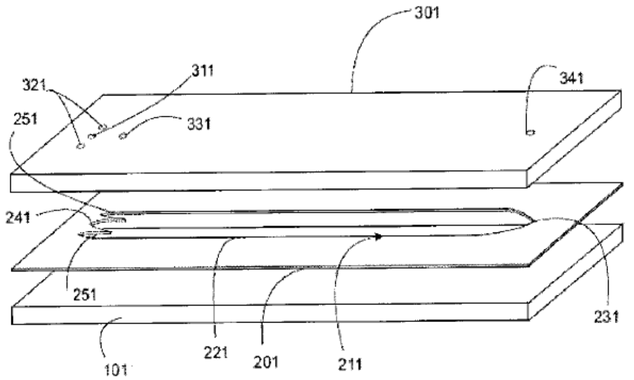


Fig. 3

(57) Abstract: The present invention relates to a device and a method for dynamic fractionation of a dispersed phase in a fluid. The device comprises a fractionation channel and from a first to a third injection ports. A first and a second confining fluids are injectable through the first and second injection ports, respectively. An elution fluid for transporting the dispersed phase is injectable into the channel through a third injection port which is arranged between the first and second injection ports. An end portion of the channel comprises from a first to a third terminal portion respectively arranged in correspondence to the first to the third injection ports and having a geometry such that the first and second confining fluids respectively have a first and second predefined flow rate and the elution fluid have a third predefined flow rate which is larger than the first and second predefined flow rates.

Problem

- Cell products for therapeutic use are considered drugs (Advanced Therapy Medicinal Products - ATMPs).
- Quality control and safety measures are mandatory.
- Methodologies to purify, count, select and collect living cells are not as yet present on the market when clients' requirements are the following:

- minimal manipulation criteria

- no modification of viability and cell properties

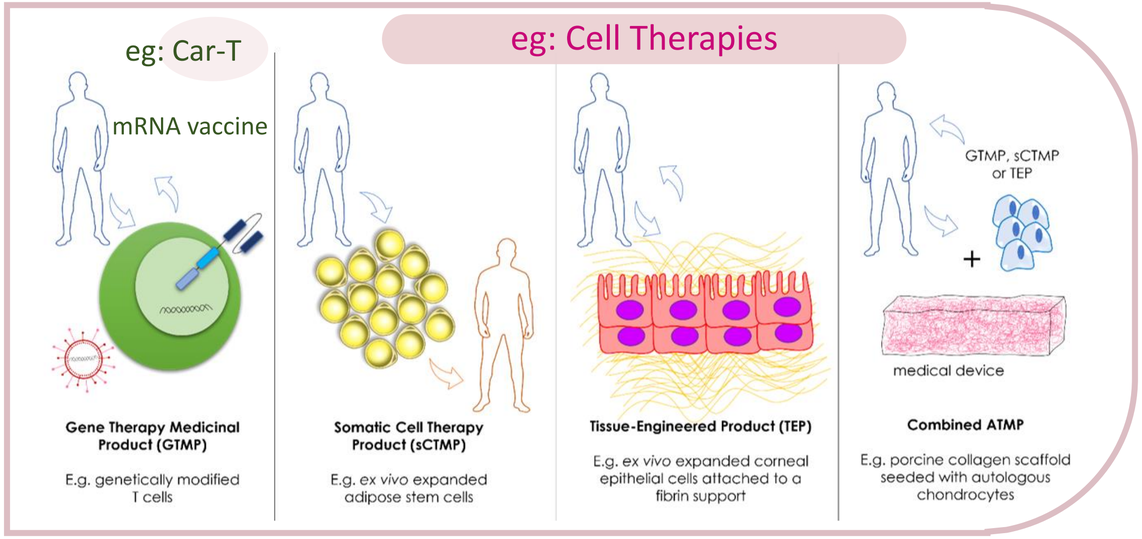
- work on complex biological samples

Solving

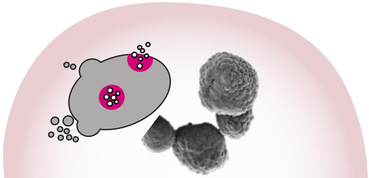
Celector® is our solution to cell SORTING and PURIFICATION and their QUALITY CONTROL in ATMPs.

Celector® ***Lab*** is already on the market to answer the unmet needs of **QC and analysis** of **cell products for ATMPs.**

ATMP Market

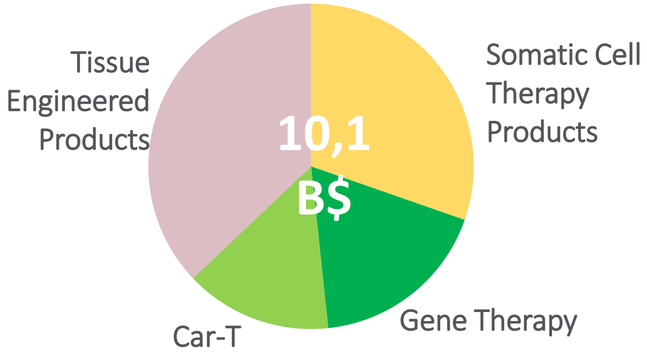


NEW ATMP FRONTIERS



Other Precision Advanced Therapies based on the study and use of organoids, extracellular vesicles, and secretome

Global ATMP Market 2022 (%)*



CAGR (2022 – 2028): 13%

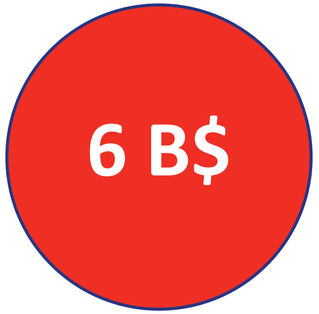
*Advanced Therapy Medicinal Products Market Size, Share & Trends Analysis Report by Therapy Type (CAR-T, Gene, Cell, Stem Cell Therapy), by Region (North America, Europe, APAC, ROW), and Segment Forecasts, 2021 - 2028

Stem Cell Therapy

- **Stem cells repair tissue and organs** and are increasingly used to **treat degenerative diseases**
- Stem cells mimic organ behavior to test **new drugs**
- Stem cells are used in the field of **Tissue-Engineered Products, Somatic Cell Therapy Products** and **Combined ATMPs**

Global Stem Cell Market*

2022



CAGR

- **Cell and Tissue Cell banks: 12,6%**
- **Clinical Application: 8,5% (10,7% Asia/Pacific)**

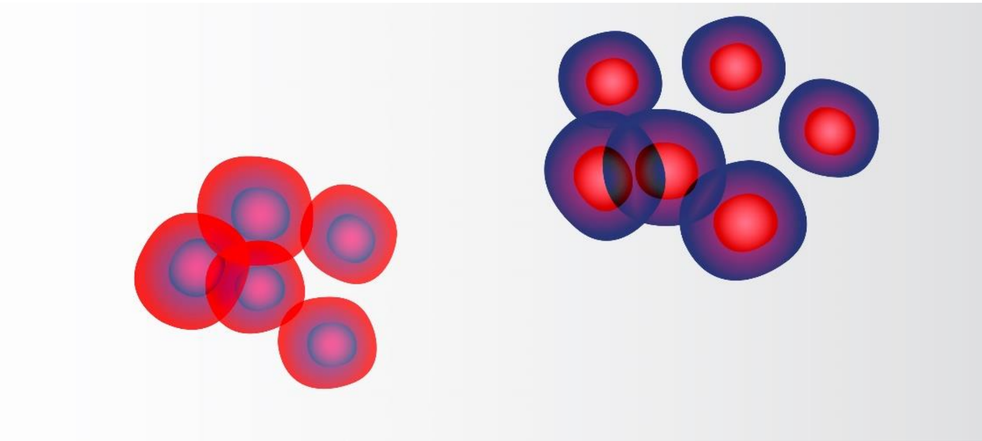
CONSUMABLES AND INSTRUMENTS

8,5% (10,7% Asia/Pacific)

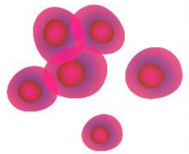
The **principal key players** are Cell Applications Inc., Cyagen Biosciences Inc., Axol Bioscience Ltd., Cytori Therapeutics Inc., Stem Cell Technologies Inc., Celprogen Inc., BrainStorm Cell Therapeutics Inc., Stemedica Cell Technologies Inc.

*Advanced Therapy Medicinal Products Market Size, Share & Trends Analysis Report by Therapy Type (CAR-T, Gene, Cell, Stem Cell Therapy), by Region (North America, Europe, APAC, ROW), and Segment Forecasts, 2021 - 2028

Celector®/ Applications



CELL-BASED ATMPs

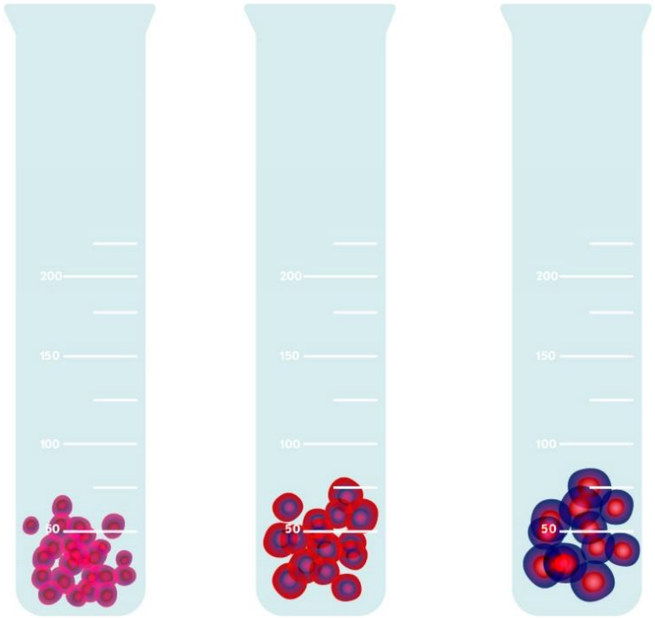


Quality control and selection of target cells

→ Optimize the production of patented «best cells»

→ Decrease production time and costs by 50%

- Increase production's contribution margin
- Follow regulatory compliance
- Ease the achievement of GMP requirements (Good Manufacturing Practice)
- Reduce the risk of failure to reach clinical trial phase



PHARMA

Optimize the production of stem cells and organoids used as a model for «drug discovery»

→ Strength the "in vitro" drug test efficacy, robustness and descriptiveness of new drugs for patients

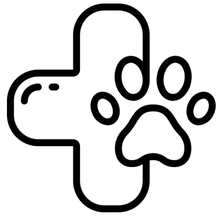
Celector®/ Target clients

BIOTECH AND PHARMACEUTICAL COMPANIES

HOSPITAL AND SURGERY CENTRES

ACCADEMIC LABS, RESEARCH LABS AND CRO

CELL AND TISSUE BANKS



OTHERS (EG: VETERINARY)

Celector®/ Selection of MSCs from bone marrow

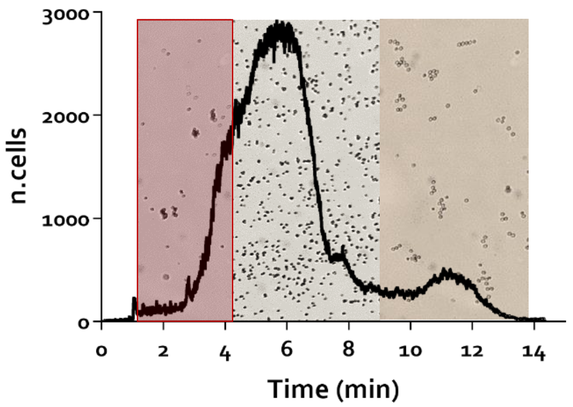
Quality Control and Selection of «elusive to tag» cells for *in vitro* or *in vivo* applications

- Cell isolation and separation from **«raw» ex-vivo samples**
- Real-time images acquisition and cell counting using a micro-camera (**sample cellularity**)
- **Select & Collect different sub-populations of «elusive to tag» cells** at a rate of 2.5 millions processed cells/hour.

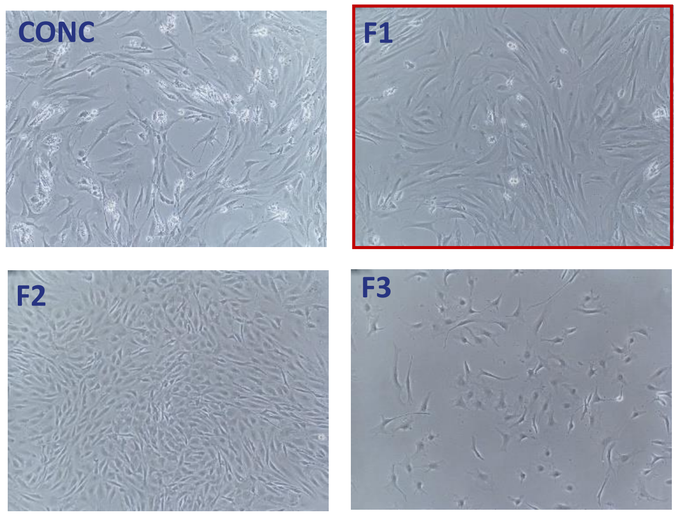
Bone marrow concentrate (using IOR G1 by Novagenit srl)
In collaboration with RAMSES Lab, Rizzoli Institute (Bologna)

Zia S. et al. Effective Label-Free Sorting of Multipotent Mesenchymal Stem Cells from Clinical Bone Marrow Samples. Bioengineering (Basel). 2022

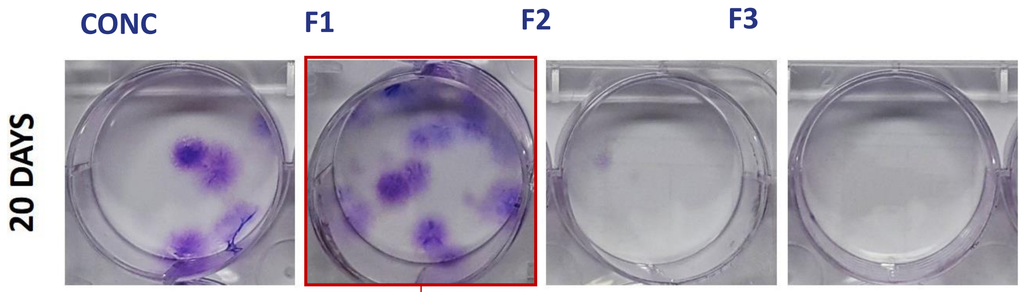
BMC: CELECTOR® PROFILE

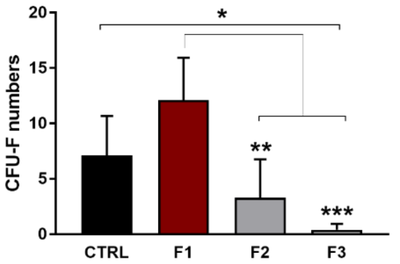


MORPHOLOGY



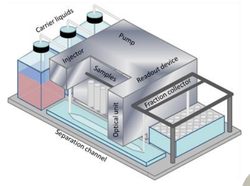
CFU-F





SELECTION AND COLLECTION OF THE "BEST" STEM CELLS FOR A CARTILAGE RECONSTRUCTION CLINICAL TRIAL

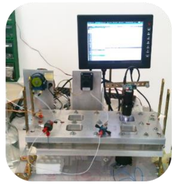
Celector® / The evolution



TRL 2

2013

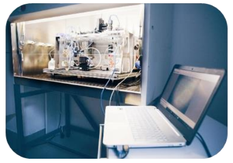
TRL 3



2014

TRL 7

Aprile 2019



Nov. 2020: Market-Ready

CE

TRL 9

Nov 2020

Conclusion of conformance test

Instrument production for biological validation

Dec 2021

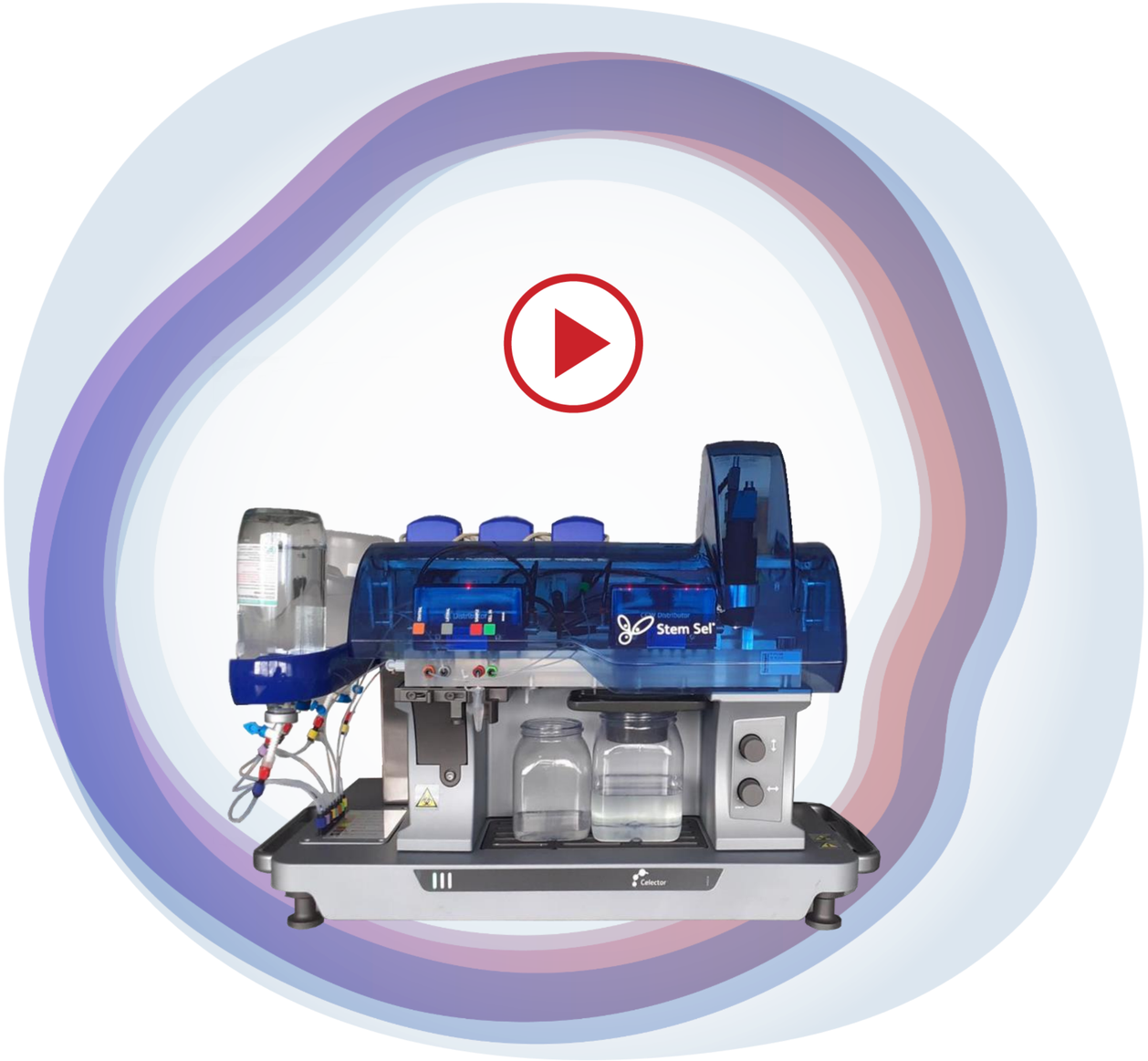
Certified biological validation

Sept 2024

Summer 2025

GMP Certification start

Celector®*Lab* / How it works



Stem Sel®

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