

Press release



## **Cook Regentec and Asymptote Introduce the CellSeal® Automated Thawing System**

*Enables detailed control in thawing of cell and gene therapies*

**Indianapolis, US, and Cambridge UK, 29th November 2016:** Cook Regentec, focused on developing research and clinical tools to advance regenerative medicine therapies from the lab to the patient, and Asymptote Ltd., specialists in cryochain for regenerative medicine, today announced the launch of the CellSeal® Automated Thawing System. The new system, which has been developed as part of a collaboration between the two companies, provides users with thorough control in the thawing of cryogenically frozen cells, a critical step in the delivery of cell and gene therapies.

The CellSeal® Automated Thawing System solves a vital and overlooked aspect of cell-based therapy development. The current practice of thawing these potentially fragile, living therapies relies on a manual process using a water bath. The new system works through dry conduction with no need of water, a potential source of contamination, and provides an effective, reliable and scalable solution which supports Good Manufacturing Practice (GMP) requirements.

The CellSeal® Automated Thawing System has demonstrated performance. In a recent study with mesenchymal stem cells (MSC), the system consistently equaled viability results obtained from water bath thawing. The system's effectiveness comes from the extraordinary control it provides over the thawing process. Therapy manufacturers can tune a thaw profile to suit the specific needs of their cellular therapy, then lock the profile down for one-touch repeatability. The system removes any user subjectivity by detecting the precise thaw end-point—extremely difficult to achieve using the standard water bath process. The technology offers manufacturers consistent control over the thawing process of their cell therapy.

An important feature of the new system is instant access to vital data. Until this new system, the collection and collation of data from thaw sites, often using paper records, could produce significant challenges to cell and gene therapy manufacturers. Now, data recording in each CellSeal® Automated Thawing System captures a record of the thaw process. With appropriate software, hardware and connectivity, this data can be viewed anywhere in the world to validate and implement a manufacturer's end-to-end thawing protocol.

**Brad King, Director of Advanced Laboratory Products at Cook Regentec, explained the challenge:** "We created our CellSeal® product line to support cell and gene therapy companies through every bioprocessing step. Thawing of cryopreserved therapies often happens outside the lab in conditions that up to now have been very difficult to control; thaw-site personnel have had to take great care to avoid contamination risks from the use of warm water. Also, manually produced records for thawing and administering the product at a remote site can take a long time to return to a manufacturer, if they are returned at all. The CellSeal® Automated Thawing System makes it easy to ensure an effective, controlled and auditable thaw."

Cook partnered with Asymptote for the technology behind the thawing system because of their long established cryopreservation expertise and innovative cryochain technologies for regenerative medicine.

**John Morris, Asymptote CEO shared some details:** “Today’s announcement builds on thawing technology we have been working on for over two years in collaboration with The Cell and Gene Therapy Catapult. Over that period, Asymptote built many different thawing engines for testing at the Catapult labs and captured requirements from a wide cross-section of stakeholders across the industry. By partnering that foundation with Cook Regentec’s development of closed-system vials, we’re able to offer the industry a unique level of control over the thawing process. No other solution allows the same flexibility to customise thawing settings in the lab, then lock them down for quick and easy operation every time after. Combine this with the ability to transmit a record of the entire process instantly to a web browser anywhere in the world, and you have a system that can give manufacturers complete confidence in their thawing protocol.”

The CellSeal® Automated Thawing System will be on display at the Cell Therapy Manufacturing & Gene Therapy Congress, Amsterdam on 29 & 30 November 2016 with first shipments in January 2017.

**Ends**

**Notes to Editors.**

**Photo:** CellSeal® Automated Thawing System. For a high res image please contact [lorna.cuddon@zymecommunications.com](mailto:lorna.cuddon@zymecommunications.com)



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**About Cook Regentec**

Cook Regentec is focused on developing research and clinical tools to advance regenerative medicine therapies from the lab to the patient. Our team originated at Cook Medical, a medical device company that has worked with researchers and physicians for more than 50 years to develop more effective therapeutic tools. Cook Regentec's starting range of products includes cellular growth media, solutions for cryopreservation, and medical devices for the delivery of therapeutic agents. For further information visit [www.cookregentec.com](http://www.cookregentec.com)

**About Asymptote**

Asymptote combines world leading research into the science of cell freezing with engineering expertise to create pioneering cryochain technology for advanced medicines. Our portfolio of innovative products preserve cell viability during cryogenic processing of cellular therapies – their freezing, shipping and thawing – to support our customers' work to improve healthcare throughout the world. For further information visit [www.asymptote.co.uk](http://www.asymptote.co.uk)