IMPORTANT RESTRICTIONS for the use of our products or deliveries (2015)

A. All devices, attachments and parts of the devices are provided non-sterile. If sterilization is desired, sterilization is to be validated and performed by the client or its affiliates prior to use.

B. The devices may be labeled "non-sterile, for Investigational Use under IRB Only".

C. The materials purchased for the production and used during production are to be selected by the client. StemCell Systems is not responsible for biocompatibility or toxicity testing and can not provide information on nor guarantee biocompatibility or non- toxicity.

D. Use of all the delivered prototypes, devices, attachments, or SOPs is restricted to regulatory body approved use. Regulatory bodies include CE Mark Notified Bodies or the FDA. CE Notified Bodies or FDA registered clinical studies are to be performed only by the responsible surgeon / MD in the framework of a controlled clinical study, that was presented at the local institutional review board (IRB) or Ethical Committee and the regulatory body. For obtaining a specific permission a specific permission is required, e.g. an investigational device exemption (IDE). IDE and IRB approvals have to be obtained by the customer prior to using the devices. For such applications, it is important to mention how a sterilization of all devices is required and where the sterilization is to be performed.

E. The devices, materials, attachments or procedures or SOPs are to be used with the primary purpose they were developed for. For example, if a device was developed for using isolated and autologous cells, only these specified cells can be used.

F. Any aspects of using the devices, attachments, methods SOPs that StemCell Systems provides relate to external medical applications only and under no circumstances an internal application should be planned or conducted.

G. It is the responsibility of the client to relay the information given here to potential partners and associates.