Vicenza (Italy), 25/11/2021

To whom it may concern:

IMPORTANT UPDATES FOR THE DEVICE BIOCOLLAGEN

Dear Partner, Dear Customer,

We are contacting you to bring to your attention some important updates that have been made to our technical/regulatory documentation in reference to our Medical Device **BIOCOLLAGEN**.

In accordance with European Regulation on Medical Devices 745/2017, the **implant card** has been introduced.

The implant card is printed inside the leaflet, in as many copies as the devices contained within the package. At the end of surgery, the doctor must cut out a copy of the implant card and fill it in with the following information: patient's first and last name, date of the surgery, name of the operator who performed the surgery and address of the facility where the surgery was performed; on the back of the implant card, the doctor must then affix a copy of the patient label supplied with the Device and deliver the completed implant card to the patient. For your reference, we have attached a copy of the **new IFU in revision 21210831**.

The Device **Technical Data Sheet** has been updated with the appropriate references to the implant card and to the updated list of references that are currently produced.

Thank you for your attention.

For any clarifications, please contact us at info@bioteck.com

ISO 13485

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