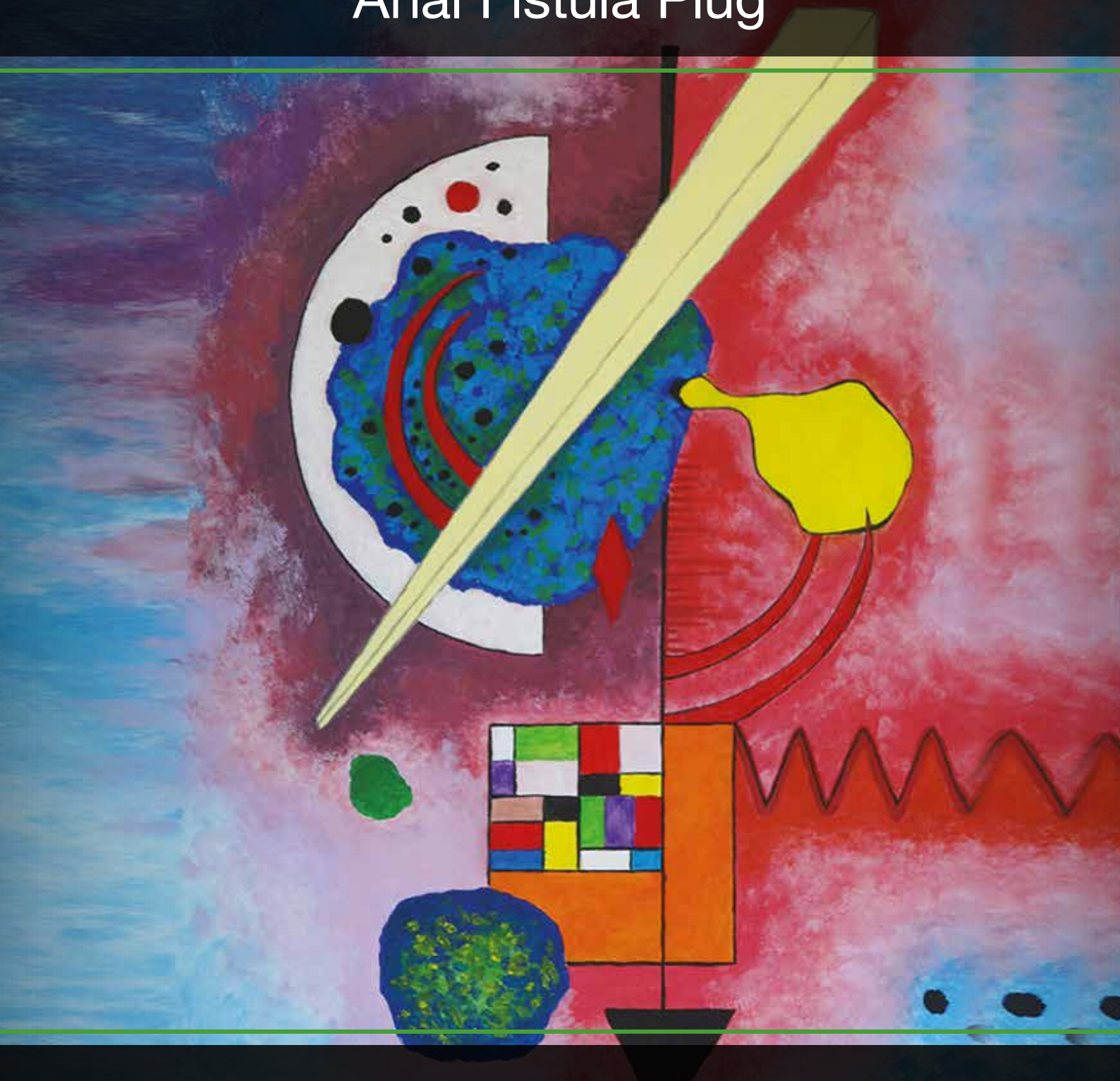


PRESSFIT[®]

Anal Fistula Plug

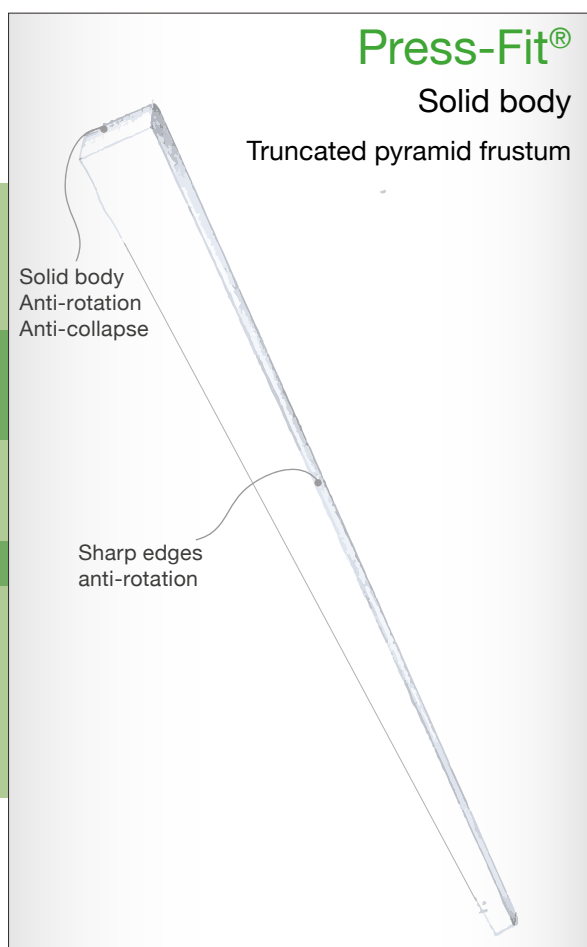


NEW BIOMECHANICAL STATE OF THE ART

Shape

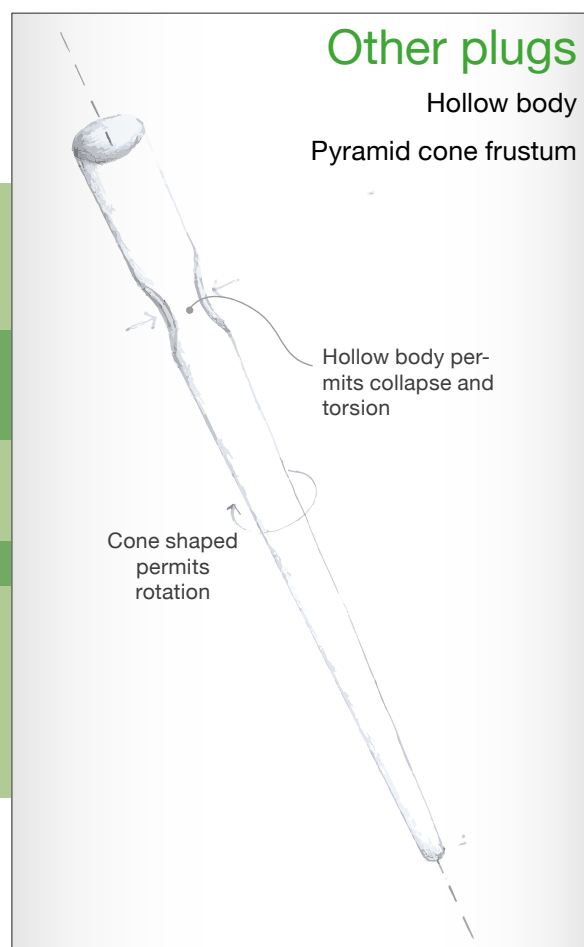
Primary stability of the plug in the fistula is a mandatory biomechanical prerequisite for healing damaged tissue.

The Press-Fit® surgical technique is based on the mechanical interference between the device and the fistula walls aimed at neutralizing the dislocation forces and ensuring a state of intimate contact between the device and the surrounding vascularized tissues.



SHAPE WHICH ENSURES PRIMARY STABILITY AND INTIMATE CONTACT

TISSUE REGENERATION



SHAPE WHICH DOES NOT GUARANTEE PRIMARY STABILITY AND INTIMATE CONTACT

FAILURE

The anti-torsion and anti-collapse solid body, the truncated pyramid frustum shape and the anti-rotation sharp edges neutralize the dislocation forces providing Press-Fit® with primary stability in the fistula tract.

Substance

Numerous studies have demonstrated that the use of inert substances does not produce the best results. Any device which is passively tolerated by the body cannot ensure tissue regeneration. For this reason the most recent studies have been geared towards the use of active substances.

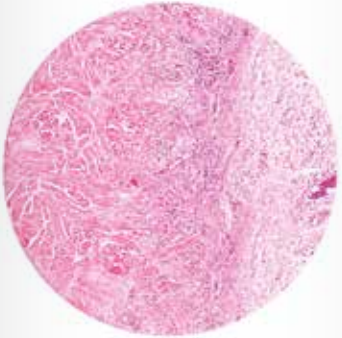
Numerous biomaterials are currently used to produce medical devices for tissue regeneration. From a biological standpoint they are classified in two categories:

Active

Natural: native proteins
Stimulate cell migration

TISSUE REGENERATION

Press-Fit® ADM plug

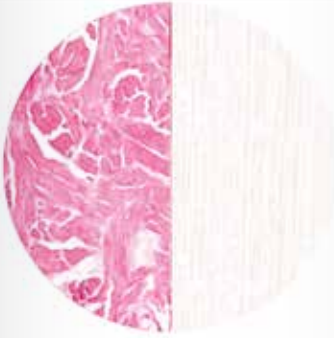


Inert

Absorbable synthetics: chemical from polymers
Passively tolerated by the body

PASSIVE DEGRADATION

Other plugs



Since Press-Fit® is natural and active it is tolerated excellently by the body.

Press-Fit® is composed of acellular dermal matrix (ADM), an active and natural substance. The material source and patented design are conceived to comply with biomechanical requirements (shape and substance) to promote tissue regeneration.

Reabsorption or Remodelling?

Biomaterial reabsorption takes place in the body following the action of collagenase lytic enzymes. It can be the final part of the biological process which lead to clinical failure or an intermediate step in the remodelling process.

The choice of biomaterial has proven to be crucial for guiding the body's repair mechanisms towards clinical success or failure.

Press-Fit® is not reabsorbed or degraded. On the contrary, thanks to its self-locking shape and native collagen, it is recognized by the body as a natural conducting tissue. It stimulates cell migration by enhancing the remodelling process.

A CHOICE OF SUBSTANCE



NATURAL biomaterial

Active

It is composed of native protein polymers (taken from mammal acellular tissue e.g. collagen). It provokes a recognition response by the body which regenerates as if it was its own damaged tissue (remodelling).

SYNTHETIC biomaterial

Inert

It is composed of polymers obtained through chemical synthesis (e.g. trimethylene carbonate, polypropylene, polyglycolic acid). It is chemically and physically tolerated by the body but biologically does not trigger regenerative processes. (Partial reabsorption/encapsulation).



Repair or Regeneration?

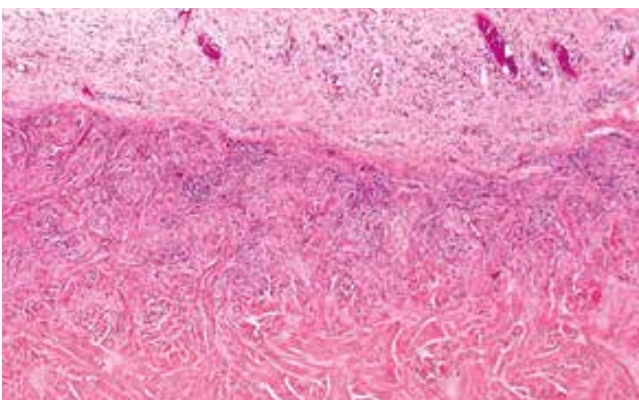


The function of the plug is to act as a scaffold for tissue healing. If it is inert (artificial or synthetic biomaterial) and unstable, the surrounding tissue triggers defence mechanisms that start with inflammatory processes and result in encapsulation with high percentages of extrusions. Repair times can be very long following repeat operations necessary for healing.



An active plug (natural biomaterial), enhanced by the use of the Press-Fit® technique, creates continuity in the fistulous tissue. Thus the regenerative biological process is activated which will lead to tissue healing based on physiological turn-over times.

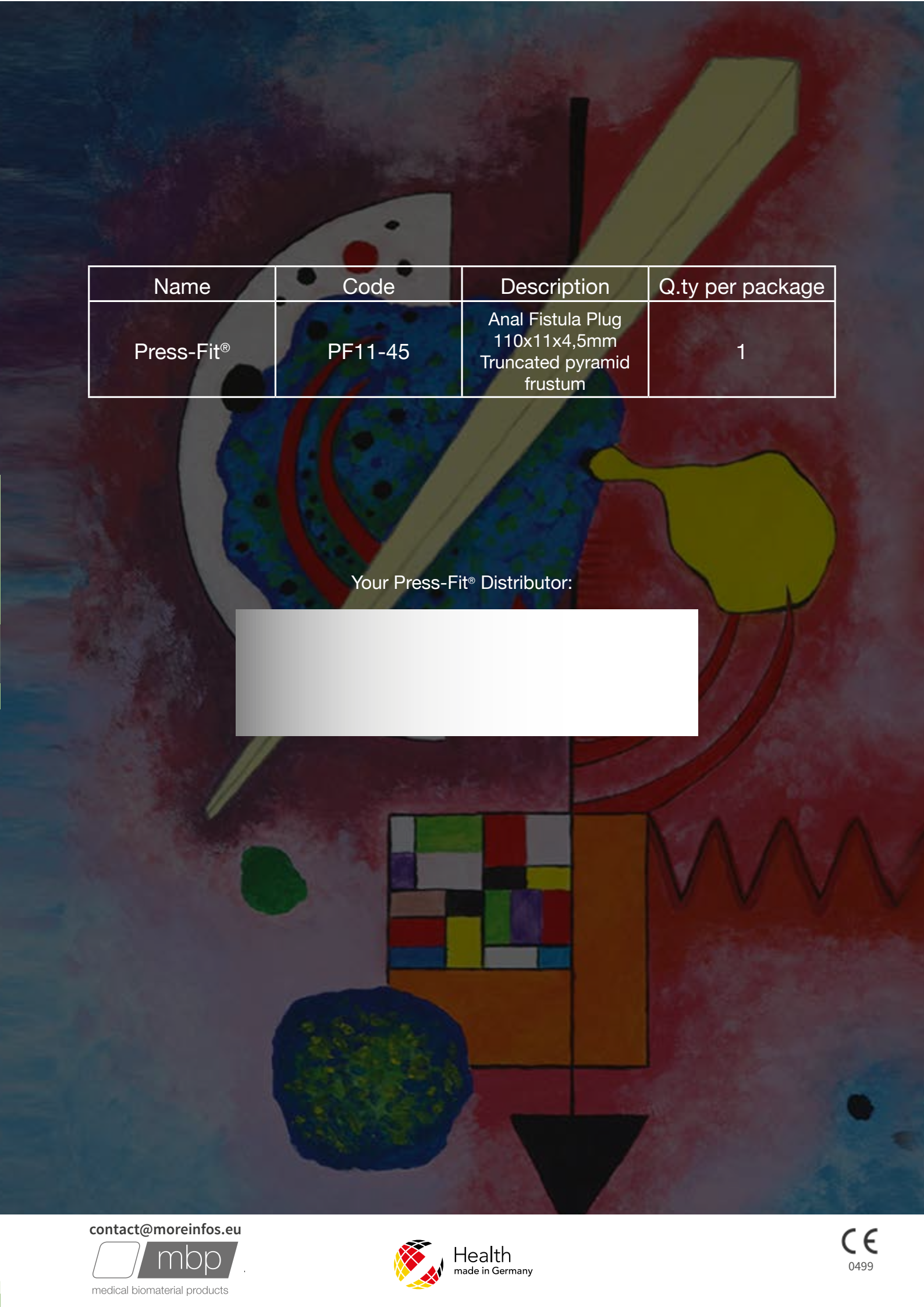
Nowadays the concept of biocompatibility is not sufficient for confirming the effectiveness of a biomaterial. Its performance must go beyond the threshold of passive tolerability. It must be active, and not inert in order to enhance the biological algorithm of Guided Tissue Regeneration.



Cell invasion on ADM sample implanted using Press-Fit® technique (2 months).

Press-Fit® is composed of native collagen fibre bundles promoting aggregation and platelets lysis. The consequent release of growth factors activates the biological process of Guided Tissue Regeneration.

Press-Fit®, as a natural ADM, maintains the pre-existing vascular network within its thickness. This allows blood to permeate the matrix accelerating cell migration and tissue regeneration.



Name	Code	Description	Q.ty per package
Press-Fit®	PF11-45	Anal Fistula Plug 110x11x4,5mm Truncated pyramid frustum	1

Your Press-Fit® Distributor:

