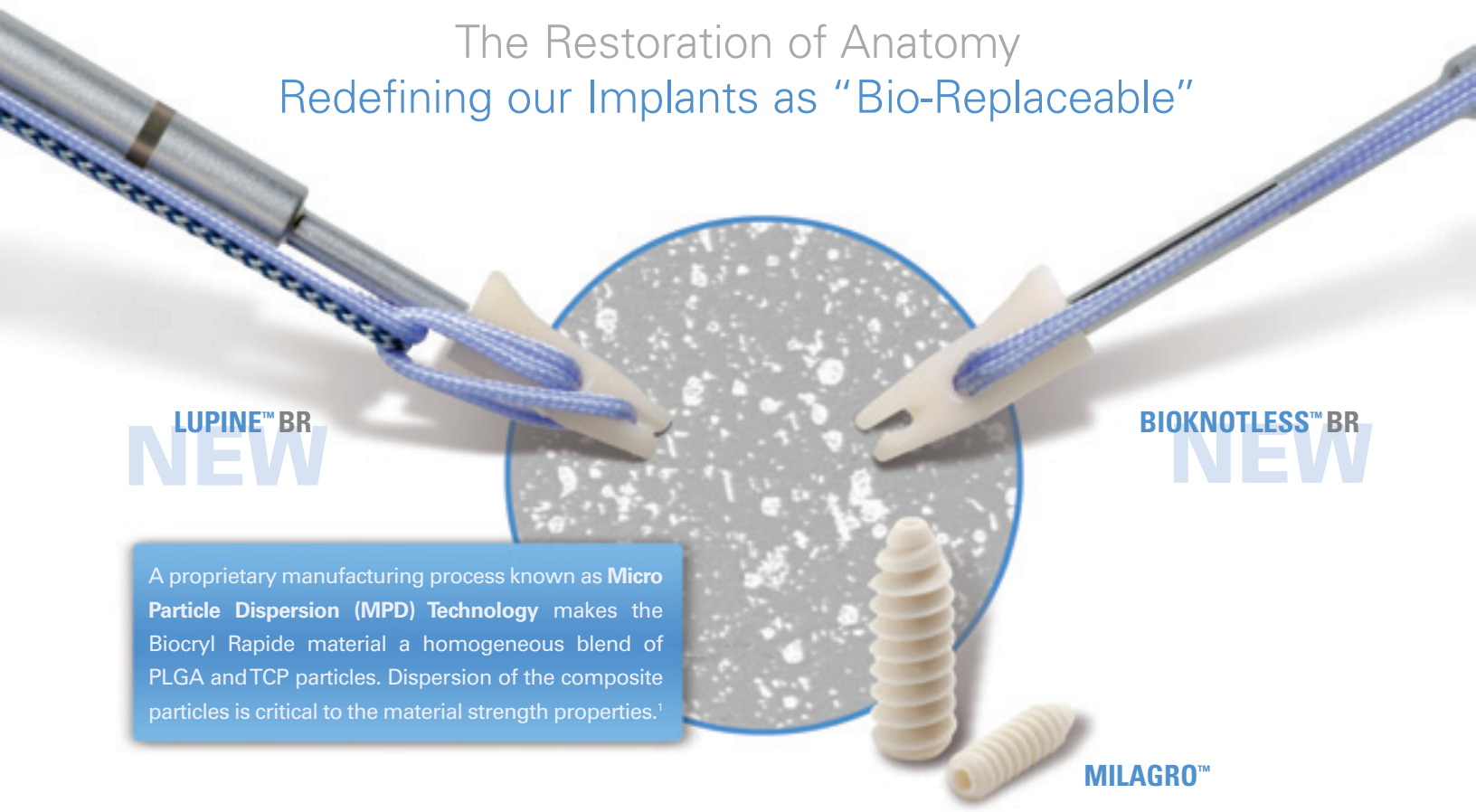
BIOCRYL RAPIDE

TCP/PLGA Composite

The Restoration of Anatomy
Redefining our Implants as "Bio-Replaceable"



A proprietary manufacturing process known as **Micro Particle Dispersion (MPD) Technology** makes the Biocryl Rapide material a homogeneous blend of PLGA and TCP particles. Dispersion of the composite particles is critical to the material strength properties.[1]

An Evolution in Sports Medicine Implants

Biocryl Rapide composite is exclusively developed by DePuy Mitek in association with the Johnson & Johnson Center for Biomaterials and Advanced Technology. It is well suited for knee and shoulder implants and will be useful whenever the advantages of a "bio-replaceable" implant prove to offer a procedural advantage by aiding in the restoration of anatomy.

DePuy Mitek
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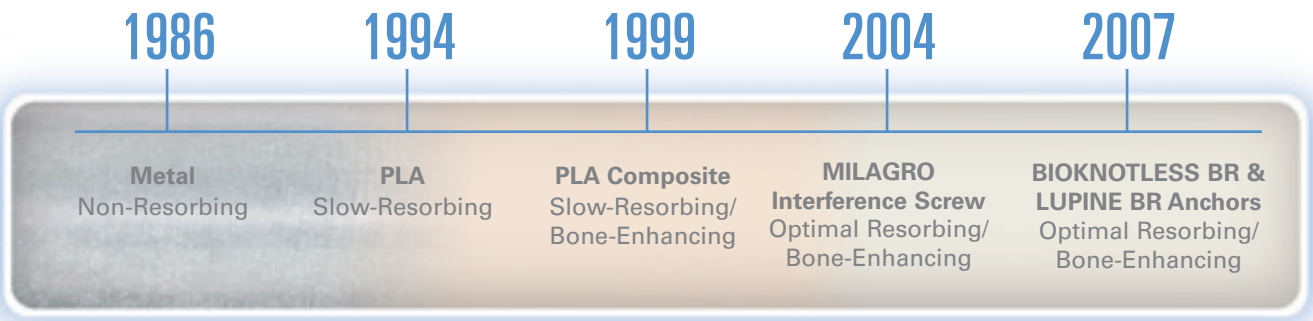
An Evolution in Materials...

Biocryl Rapide is an evolution in materials technology. Implants for sports medicine applications, such as shoulder anchors or interference screws, were first developed using metal. However, metal implants can distort magnetic resonance imaging; complicate revision procedures due to their presence; and are non-resorbing.

Resorbable polymers, such as polylactic acid (PLA) were introduced to overcome these objections by allowing for biodegradation. In spite of its benefits, PLA has been associated with an extended period for implant resorption and is not an osteoconductive material.

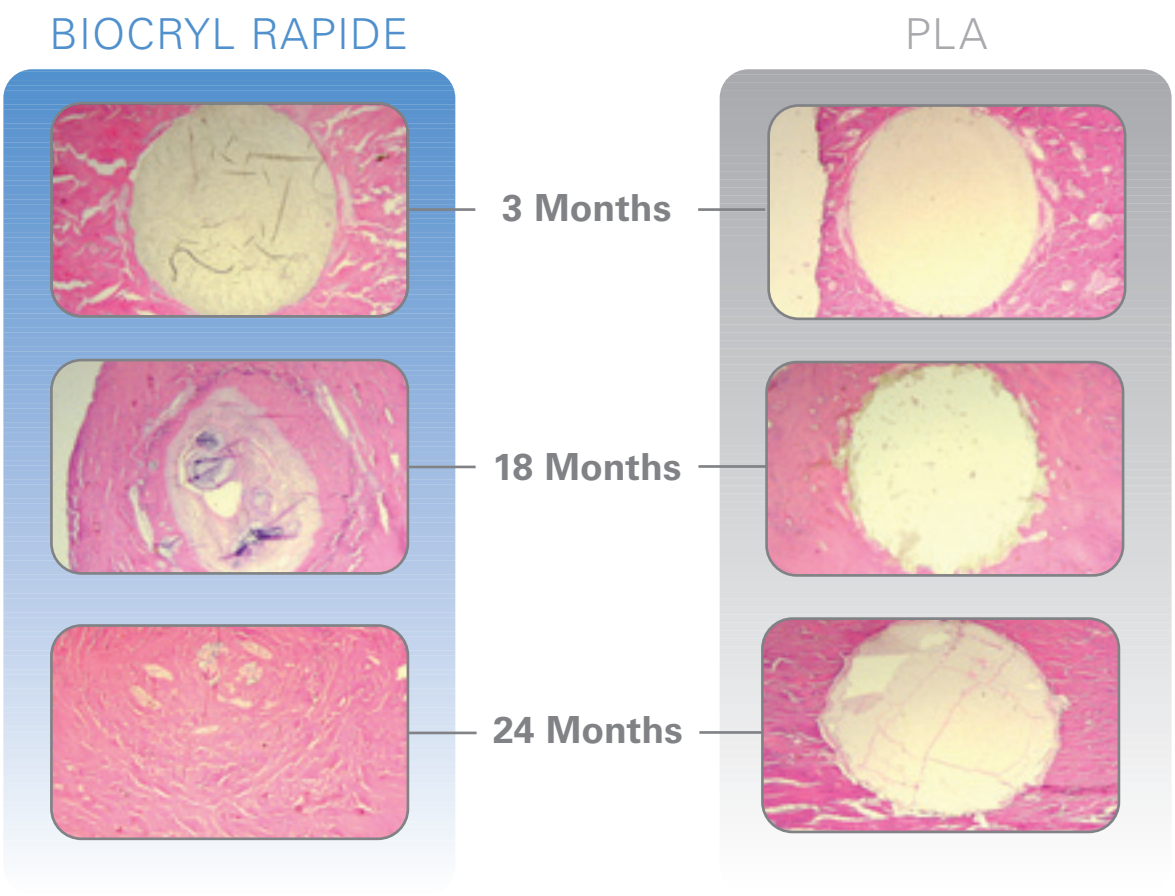
To improve upon PLA, composite materials comprised of PLA and osteoconductive bioceramics, such as ß TriCalcium Phosphate (TCP) were introduced. These materials are not only resorbable, but also have the benefit of osteoconductive bioceramics — which facilitate biologic incorporation of bone.

Improving further on PLA and PLA composites, Biocryl Rapide is a second-generation composite material comprised of 30% TCP and 70% of the faster-resorbing copolymer, PLGA. In long-term pre-clinical studies, Biocryl Rapide has been shown to completely resorb and to promote bone formation within the implant profile[1].



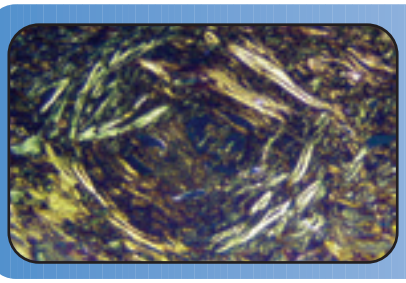
Biocryl Rapide vs PLA[1]

In a long-term, controlled study, Biocryl Rapide and PLA materials were evaluated in cortical femoral bone of Beagles[1]. Following implantation, sections of the implant sites were examined histologically as seen below.



Biocryl Rapide's absorption progressed from minor changes at 3 months to marked absorption by 24 months. Following absorption, bone formation was seen within the implant profile. By comparison, PLA implants exhibited significantly slower absorption over time.

The same Biocryl Rapide 24 month image seen above was viewed under polarized light. In the image below, newly formed bone can be seen as the cells begin to align in patterns similar to the native bone.



Biocryl Rapide at 24 months

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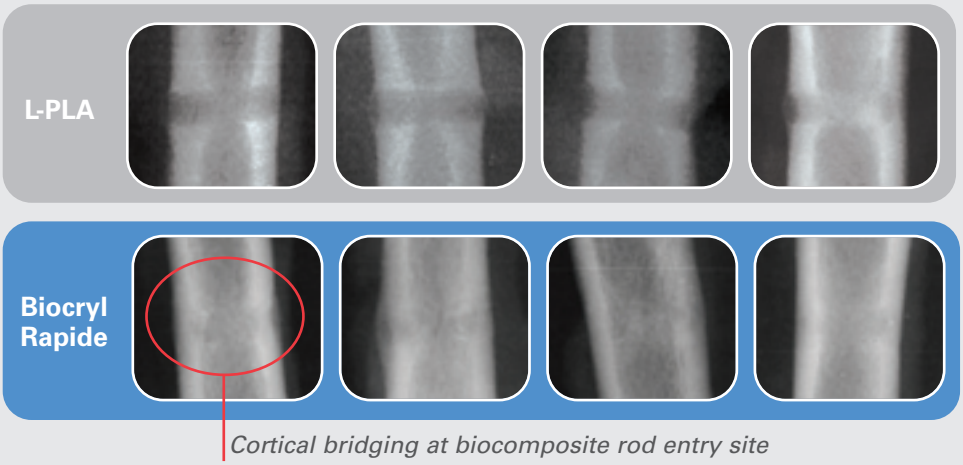
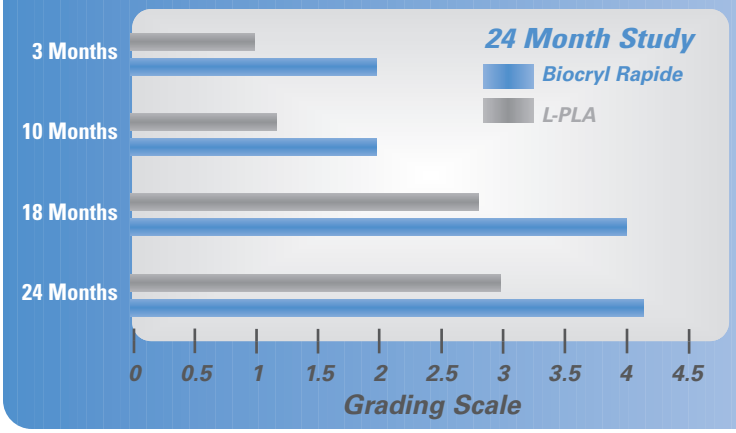
BIOCRYL RAPIDE

Biocryl Rapide has demonstrated long-term compatibility in the canine transcortical femoral rod model.[1]



Biocomposite rods of Biocryl Rapide are biocompatible in beagle femoral bone out to 24 months.

By 24 months, nearly the entire cross-section of the Biocryl Rapide test rods in cortical bone had been absorbed and replaced by either normal bone or bone with fibrous or adipose tissue. While in comparison, the L-PLA test specimens showed only minimal absorption.



Grading Scale:

1- No apparent change
2- Minor CIEF
3- Moderate CIEF
4- Marked CIEF
4.5- Only trace amounts remain
5- No recognizable material remained

CIEF = cracks, cell infiltrations, erosions and/or fragmentation

RESULTS: MARKED ABSORPTION

The Biocryl Rapide material exhibited marked absorption from 18-24 months[1], accompanied by a gradual increase in the proliferation of mesenchymal cells that differentiated toward the osteoblastic line.

Material Processing

DePuy Mitek utilizes pure medical grade ß-tricalcium phosphate for the Biocryl Rapide material. Biocryl Rapide does not contain fillers, such as magnesium oxide, which may be present in competitive composite materials.

A proprietary manufacturing process known as Micro Particle Dispersion (MPD) Technology makes the Biocryl Rapide material a homogeneous blend of PLGA and TCP particles. Dispersion of the composite particles is critical to the material strength properties[1]. Non-homogeneous composites may result in a material with compromised or variable strength properties due to stress risers within the material[1].

Summary

Biocryl Rapide is a composite material combining TCP and PLGA. Pre-clinical testing has shown complete absorption over time, followed by bone in-growth[1]. Biocryl Rapide with its inherent bioabsorbable, osteoconductive properties is a good choice for a continuum of sports medicine implants to aid in the restoration of anatomy.

Now available with Biocryl Rapide…

- *BIOKNOTLESS™ BR Anchor*
- *LUPINE™ BR Anchor*
- *MILAGRO™ Interference Screw*

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[1]Data on file.