

Anika. Restore Active Living.™



**Tactoset**®

*Injectable Bone Substitute*

Value analysis committee | Product information kit

# Product attributes

Material											
Calcium phosphate	Remodels to hydroxyapatite, the mineral component of bone <sup>6</sup>										
Hyaluronic acid	Enhances flowability and interdigitation in trabecular architecture <sup>6</sup> Provides tactile feedback when injecting into the bone void <sup>6</sup>										
Osteoconductive	Supports endogenous cell-mediated bone remodeling and growth of new bone into the bone void <sup>5,6</sup>										
Mixing											
Closed mixing system	Minimizes environmental exposure <sup>6</sup> Enhances ease of use: no mixing bowls; no mess <sup>6</sup>										
Use											
Multi-angle access cannula	Allows surgeons to easily switch intraoperatively between side and end Tactoset delivery without having to remove and reinsert the outer cannula <sup>6</sup>										
Mix and use time	1 min mixing time; 6 min waiting time; 11 min injection time; 10 min setting time										
Performance											
Compressive strength	Compressive strength of Tactoset is similar to that of cancellous bone <table border="1"> <thead> <tr> <th></th> <th>Tactoset</th> <th>Cancellous bone<sup>9</sup></th> <th>Proximal Tibia (Trabecular Bone)<sup>9</sup></th> <th>Proximal Femur (Trabecular Bone)<sup>10</sup></th> </tr> </thead> <tbody> <tr> <td></td> <td>8 MPa</td> <td>2-12 MPa</td> <td>5.3 MPa</td> <td>6.8 MPa</td> </tr> </tbody> </table>		Tactoset	Cancellous bone <sup>9</sup>	Proximal Tibia (Trabecular Bone) <sup>9</sup>	Proximal Femur (Trabecular Bone) <sup>10</sup>		8 MPa	2-12 MPa	5.3 MPa	6.8 MPa
	Tactoset	Cancellous bone <sup>9</sup>	Proximal Tibia (Trabecular Bone) <sup>9</sup>	Proximal Femur (Trabecular Bone) <sup>10</sup>							
	8 MPa	2-12 MPa	5.3 MPa	6.8 MPa							
Reaction temperature	Non-exothermic setting reaction; no increase in local temperature or tissue necrosis <sup>6</sup>										
Porosity (when fully cured)	 <p>49.93% ± 0.43% SEM image of set Tactoset at 6000X Tactoset sets to a nano-sized, poorly crystalline, interlocking, interconnected structure that is typical of that of hydroxyapatite-forming calcium phosphate bone void fillers. Evidence of porosity is visible.<sup>6</sup></p>										
Pullout testing	Two-fold strength enhancement for 4.5 mm PEEK anchor at 24 h in 10 PCF solid foam model <sup>6</sup> <b>Augmented by Tactoset: 222.31±13.99 N    Unaugmented: 108.17 ± 11.63 N</b>										

## References

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### Authorized Representative



**CIMed Healthcare Sdn. Bhd.**  
C-6-1 & C-6-3A Lobby C, Melawati Corporate Centre, Lot 29242, Jalan Bandar Melawati,  
Taman Melawati, 53100 Kuala Lumpur.  
Tel: +603-4101 0668 Fax: +603-4161 5685  
[www.cimedhealthcare.com](http://www.cimedhealthcare.com)



# Therapy advantages

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Tactoset supports cell-mediated regeneration of new bone as material is resorbed<sup>5,6</sup>

## Enhanced flowability and injectability

- Contains hyaluronic acid (HA), a naturally occurring substance in the human body<sup>7</sup>
- HA enhances delivery of the calcium phosphate
- Highly flowable and easily injectable through minimally invasive surgery<sup>6</sup>
- Provides tactile feedback to confirm filling of the bone defect<sup>6</sup>
- Interdigitates into trabecular bone architecture to fill closed bone voids<sup>5,6</sup>

## Closed mixing system

- Minimizes environmental exposure<sup>6</sup>
- Enhances ease of use: no mixing bowls; no mess<sup>6</sup>

## Unique cannula design

- Allows surgeons to easily switch intraoperatively between side and end Tactoset delivery without having to remove and reinsert the outer cannula<sup>6</sup>



**Tactoset<sup>®</sup>**  
*Injectable Bone Substitute*

# Tactoset introduction

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## Condition overview

- Bone voids, also known as bone marrow lesions (BMLs), represent focal edema in the subchondral bone<sup>1</sup>
- Causes include trauma, insufficiency fractures, degenerative cartilage lesions<sup>1</sup>
- BMLs have been linked with significant pain, cartilage degeneration and the progression of osteoarthritis<sup>2,3</sup>
- Studies have shown that BMLs are associated with an increased risk of total knee replacement<sup>3,4</sup>

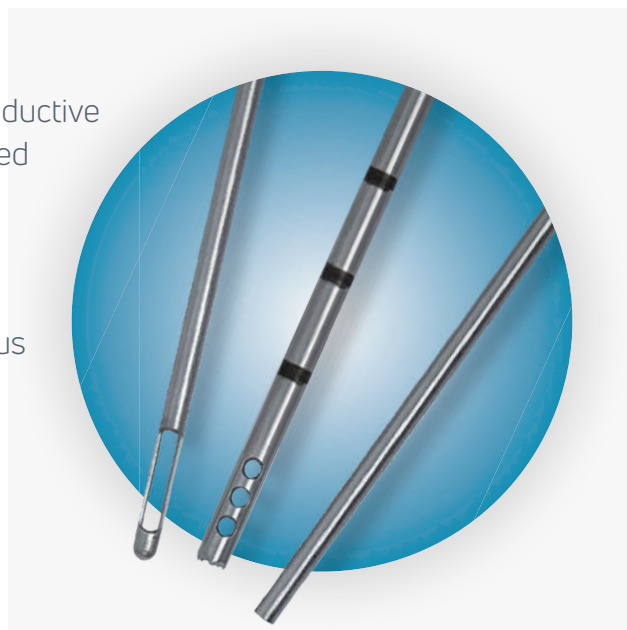
## Diagnosis

- X-rays are commonly used to determine severity of osteoarthritis, however BMLs cannot be detected on X-ray<sup>2</sup>
- BMLs can be identified on fluid sensitive, fat suppressed magnetic resonance imaging (MRI)<sup>1,2</sup>
- Recognized as an area of intense signal visible on T2-weighted sequences<sup>4</sup>



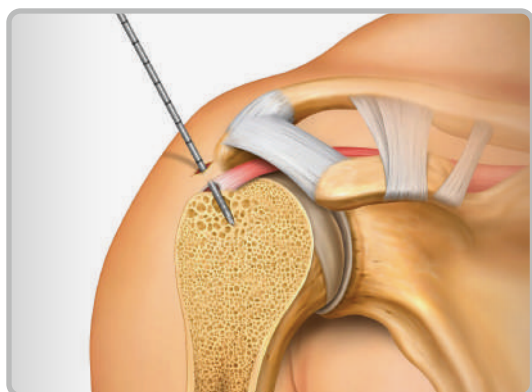
## Technology overview

- Calcium phosphate injectable, self setting, osteoconductive biocompatible bone graft substitute material intended for permanent implantation<sup>5,6</sup>
- Indicated for filling bone voids or defects of the skeletal system that are not intrinsic to the stability of bony structure, such as surgically created osseous defects or defects created from traumatic injury to the bone<sup>5</sup>
- Hardens post deployment to reinforce weaknesses such as those created by bone voids<sup>6</sup>
- Converts to a poorly crystalline hydroxyapatite at body temperature<sup>5</sup>
- Resorbs and is replaced by the growth of new bone during the healing process<sup>5</sup>



## Augmenting with Tactoset drives surgical confidence

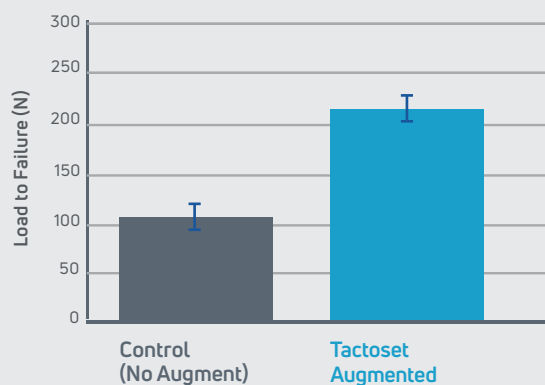
- Tactoset<sup>®</sup> Injectable Bone Substitute can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process<sup>5</sup>
- Increases the density of poor-quality bone caused by cysts or osteoarthritis, resulting in additional suture anchor pull-out strength
- Allows for placement of anchors in the ideal repair location, eliminating the need for extra anchors or complex techniques



*Representation of anchor augmented with Tactoset within trabecular bone*

### Anchor Pullout Strength

*4.5mm Twist PEEK Screw-In Suture Anchor in 10 PCF Solid Foam Block*



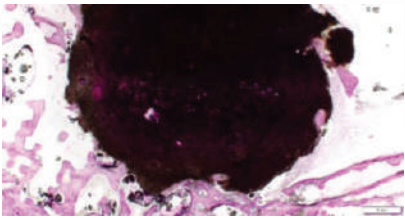
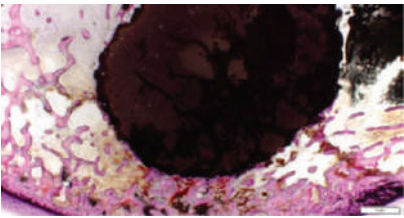
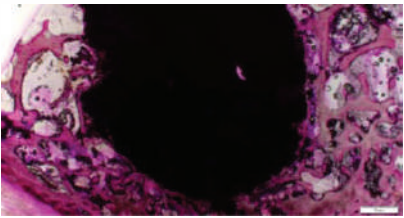
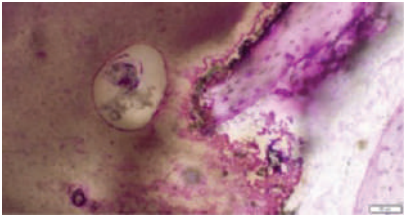
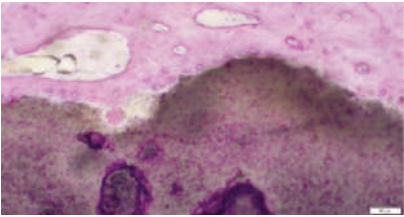
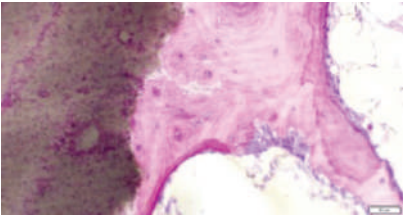
*Tactoset has been shown to double soft tissue anchor pullout at body temperature after 24 hours*

# Preclinical data

## Study purpose and design<sup>6</sup>

Evaluate the *in vivo* performance of Tactoset in a critical size defect of the distal femoral condyle in skeletally mature female New Zealand White Rabbits. Bilateral defects, 6-mm in diameter and 10-mm deep, were created in cancellous bone of the right and left femora and Tactoset was implanted.

## Histology Results *PMMA Histology Tactoset*

Time 0	Time 6 weeks	Time 12 weeks
The scale bar in these images is 1 mm		
		
The implant is well placed within the defect.	Tactoset is present in the defect with new bone on-growth directly on the material. No fibrous interface was seen. No adverse reactions were noted.	Tactoset is present in the defect with new bone on-growth directly on the material. No fibrous interface was seen. No adverse reactions were noted. By 12 weeks, bone on-growth is covering much of the interface.
Images are 50 microns		
		
At Time 0, bone apposition has not occurred.	By 6 weeks, there is evidence of bone on-growth at the implant interface without any intervening fibrous tissue layer, demonstrating the osteoconductivity of Tactoset.	At 12 weeks, there is evidence of bone on-growth at the implant interface without any intervening fibrous tissue layer, demonstrating the osteoconductivity of Tactoset.