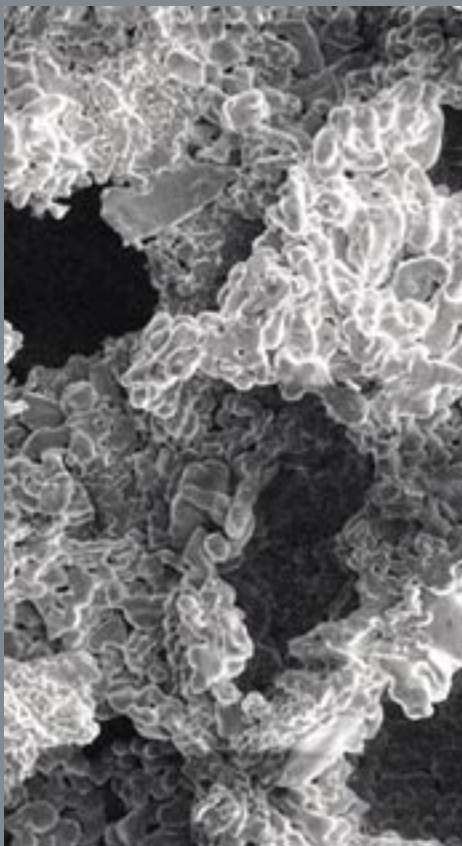
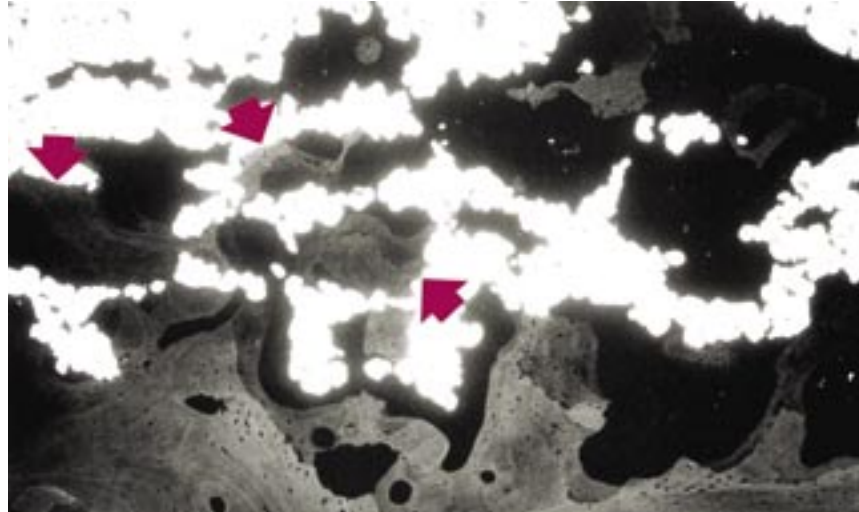


Cancellous-Structured Titanium™ (CSTi™)

An optimal structure for bone ingrowth
and fixation





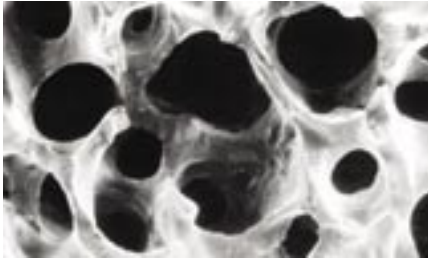
(50:1) Backscattered electron microphotograph of a section of a retrieved CSTi™-coated acetabular component. Note the direct bony attachment to the CSTi (indicated by the arrows) and the large area of neocortex at the interface.¹

“We have evidence of bone remodeling and growth into the porous coating, CSTi, and evidence of large surface areas of attachment ... all in human bone.”

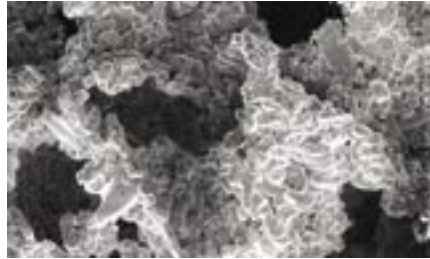
- Roy Bloebaum, PhD.

CSTi™ Porous Coating

Structurally similar to human bone



(100:1) Human cancellous bone². Pore size 400-500 μm . Pore volume 60-77%.



(100:1) CSTi. Pore size 480-560 μm . Pore volume 52-58%.

Cancellous-Structured Titanium refers to the microscopic appearance of CSTi porous coating. CSTi is structurally similar to human cancellous bone and provides interconnected pores for bone ingrowth.

CSTi porous coating combines the excellent biocompatibility of titanium with an optimal structure for bone ingrowth.

CSTi is manufactured through a proprietary process that sinters commercially pure titanium powder onto a titanium or CoCr alloy substrate. During the process, pores are created. This results in a unique porous coating that has optimally-sized, interconnected pores³ to allow bone ingrowth and a fine micro-roughness to provide secondary fixation.

The CSTi process was originally developed for a titanium alloy substrate. The Sinterlock™ process was developed to apply CSTi onto CoCr-alloy femoral knee components. This bimetal combination was a major advancement that combined the biocompatible properties of CSTi on the bone-contacting side of the implant with excellent wear properties of CoCr for the bearing surface.

Our implant designs are well matched with the CSTi porous coating technology. We offer CSTi options with several of our product lines, including: the Natural-Knee® System, Natural-Hip™ and APR® hip stems, and Converge® CSTi acetabular porous components.

Why CSTi Works

- Excellent biocompatibility of titanium
- Optimal structure for bone ingrowth
- Fine micro-roughness for secondary fixation
- Sintering process results in excellent strength and fatigue properties

Clinical Experience

Over 15 years of clinical success

Summary of Clinical Results

Date	First Author	Implant Type	Number of Implants	Implantation Time	Results
1991	Bloebaum ⁴	Tibial baseplate	1 CSTi 1 CoCr	19 mos. CSTi 25 mos. CoCr beads	67% ABI* (CSTi) 9% ABI (CoCr Beads) 22% ingrowth** (CSTi) 0% ingrowth (CoCr beads)
1991	Hofmann ⁵	Natural-Knee tibia and femur	183	2 - 4 yrs.	96% good or excellent results
1996	Baldwin ⁶	Natural-Knee	109	3 - 5 yrs.	96% good or excellent results 82% no lucencies
1997	Evanich ⁷	Natural-Knee Patella	212	6 - 10 yrs.	96% survivorship No lucencies
1997	Hofmann ⁸	Bone plug	36	Up to 1 yr.	24% ingrowth
1997	Bloebaum ¹	Acetabular shell	7	38 ± 21 mos.	84% ABI 12% ingrowth
1997	Bloebaum ⁹	Tibial baseplate	8	47 ± 36 mos.	73% ABI 6% ingrowth
1998	Bloebaum ¹⁰	Natural-Knee Patella	11	45 ± 36 mos.	86% ABI 13% ingrowth
2000	Hofmann ¹¹	Natural-Hip	90	81 ± 21 mos.	No subsidence or loosening
2000	Kang ¹²	APR-II Hip	99	45 ± 36 mos.	99% good or excellent results 94% no lucencies
2001	Hofmann ¹³	Natural-Knee	176	10 - 14 yrs.	10-yr survivorship: 99.1% femoral 99.6% tibial 95.1% patellar

*ABI (appositional bone index) is a measure of the percent of bone in direct contact with the porous surface.

**Ingrowth is determined by the percent volume of bone in the total volume of pores available. This is determined through BSE (back-scattered electron microscopy).

CSTi porous coating has over 15 years of clinical experience with demonstrated success in both retrieval and long-term clinical studies.

The excellent results in these published clinical studies confirm the basic science research supporting CSTi.

Long-term follow-up x-rays and retrieval analysis clearly demonstrate successful fixation and bone ingrowth of CSTi-coated components.



CSTi-coated hemispherical acetabular shell and Natural-Hip porous-coated collared stem. 11-year follow-up.

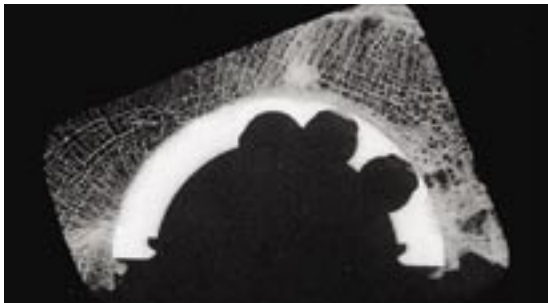
(Radiograph courtesy of Dr. A Hofmann, University of Utah, Salt Lake City).



Natural-Knee 10-year follow-up.

(Radiograph courtesy of Dr. A Hofmann, University of Utah, Salt Lake City).

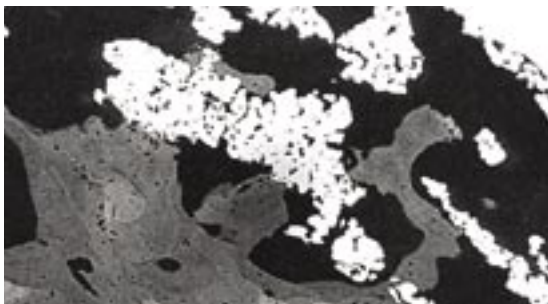
Post-mortem Retrieval Analysis of CSTi-coated Hemispherical Shell†



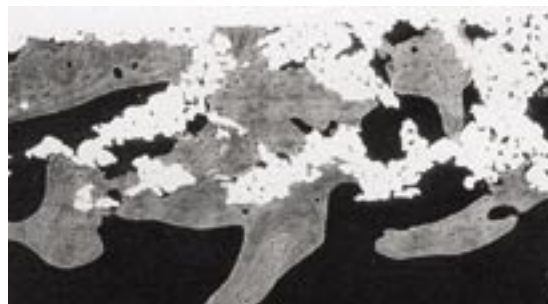
Microradiograph of a section of the shell and surrounding tissues demonstrating bone apposition.



Microradiograph of a section of the tibial baseplate and surrounding tissues demonstrating bone apposition.



(50:1) Backscattered electron micrograph demonstrating bone growth within pores of CSTi.



(50:1) Backscattered electron micrograph demonstrating bone growth within pores of CSTi.

† Retrieval micrographs courtesy of Dr. Roy Bloebaum, Bone and Joint Research Laboratory, University of Utah.

CSTi vs. Other Porous Coatings

The clinical results speak for themselves

Bone Ingrowth / Biologic Fixation Comparison



	CSTi	CoCr Beads	Ti Fiber Mesh	Plasma Spray	Trabecular Metal*
Manufacturer	Centerpulse	Howmedics Osteonics J&J Depuy	Zimmer	Biomet	Zimmer
Pore Size	400 - 600 μm	variable	-	variable	300 μm
Pore Volume	50 - 60%	35%	68%	variable	70%
Coating Material	Ti	CoCr	Ti	Ti	Ta
Retrieval Results					
% - Ingrowth Tibial Baseplates	6 - 22% ^{4,9}	6 - 9% ^{4,15}	9.5% ¹⁶	NA	NA
ABI Tibial Baseplates	73% ⁹	36% ¹⁵	27% ¹⁶	NA	NA
% - Ingrowth Acetabular Shells	12% ¹	0 - 10% ¹⁷	12% ¹⁸	NA	NA
ABI Acetabular Shells	84% ¹	NA	0-55% ¹⁸	NA	NA
Clinical Advantages and Features					
Optimal Pore Size	■				■
Optimal Pore Volume	■		■		■
Bone Ingrowth Coating	■	■	■		■
Micro-Surface Texture	■			■	■
Bimetal (Ti coating on CoCr)	■			■	
Interconnected Pores	■	■	■		■
Coating does not Disassociate	■				■*

*Trabecular Metal implants have no substrate. Polyethylene is molded directly onto the metal structure, which also eliminates the possibility of modularity.

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- Natural-Knee® System
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- UniSpacer™ Knee System
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- MOST Options™ System
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- Apollo® Hip System
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