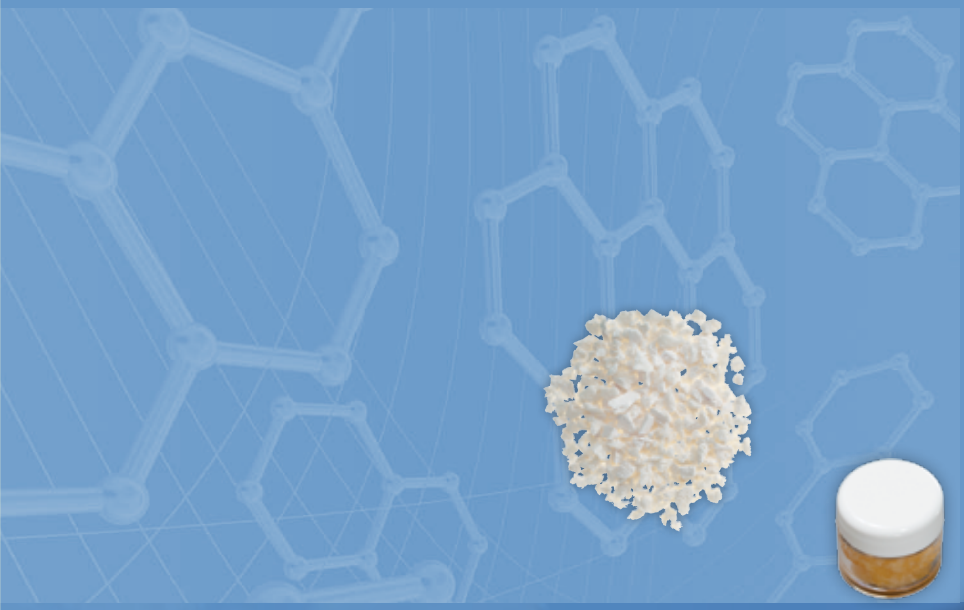
Osteobiologic Implants



RTI | BIOLOGICS®

About RTI Biologics, Inc.

- **Strong commitment to advancing science, safety and innovation**
- **Global leader in tissue-based innovations**
- **Precisely shapes allograft tissue for use in surgeries**
- **Sterilizes tissue with proprietary, validated sterilization processes that inactivate viruses—including BioCleanse® Tissue Sterilization Process, Tutoplast® Tissue Sterilization Process, and Cancelle® SP DBM Sterilization Process**

RTI Biologics, Inc. is the leading provider of sterile biological implants for surgeries around the world with a commitment to advancing science, safety and innovation. RTI prepares human donated tissue for transplantation through extensive testing and screening, precision shaping and proprietary, validated sterilization processes. These allograft implants are used in orthopedic, dental, hernia and other specialty surgeries.

RTI's innovations continuously raise the bar of science and safety for biologics—from being the first company to offer precision-tooled bone implants and assembled technology to maximize each gift of donation, to inventing fully validated sterilization processes that include viral inactivation steps. These processes sterilize tissue, are clinically successful and are scientifically proven to address donor-to-recipient disease transmission risk while preserving tissue strength and biocompatibility. They have a proven record of more than four million implants distributed with zero incidence of implant-associated infection.

RTI's worldwide corporate headquarters are located in Alachua, Fla., with international facilities in Neunkirchen, Germany, and Aix-en-Provence, France. The company is accredited in the U.S. by the American Association of Tissue Banks.

Vision

We will be recognized as the world leader in transforming donated and natural tissue into safe and innovative biologic solutions.

Mission

We improve lives by using the body to heal the body to achieve life-restoring results.

References

[1] Archibald, LA, et al., "Seroprevalence of Bloodborne Viruses Among Cadaveric Donors of Human Tissue: Implications for Tissue Safety." Presented at EATB 2005.

[2] Carr, AS, et. al., "Mechanical Testing of Soft Tissue Allografts Sterilized Through the BioCleanse Process." Unpublished data, 2005.

Table of Contents

Sterilization Processes Overview.....3-4

General Orthopedic Conventional Allografts
- Chips and Cubes.....5
- Blocks and Dowels.....6
- Wedges and Strips.....7
- Shafts.....8

Reconstructive Large Segmental Allografts
- Heads and Condyles.....9
- Proximal and Distal Grafts.....10
- Whole Bones.....11

Osteoinductive Demineralized Bone Grafts
- DBM Powder.....12
- BioReady™ DBM Putty.....12
- BioSet® DBM Allograft Paste.....13
- BioAdapt™ Foam.....13

Precision Machined Spine Spacers
- Cortical Cervical Spacer.....14

PROVEN QUALITY

The Path from Recovery to Implantation

Donor Screening

Serological & Microbiological Testing

Tissue before processing

Tissue shaped into final form

Through its innovations, RTI Biologics, Inc. (RTI) continuously raises the bar of science and safety for biologics – from being the first company to offer precision-tooled bone implants and assembled technology, to inventing fully validated sterilization processes that include viral inactivation steps. Three such processes – the BioCleanse® Tissue Sterilization Process, the Tutoplast® Tissue Sterilization Process and Cancelle® DBM Sterilization Process – have a proven combined record of more than four million implants distributed with zero incidence of implant-associated infection. Validation studies have been performed for each process based on tissue type using appropriate challenge microorganisms.

Serological Testing (for every donor):

- HCV Antibody
- HBV Surface Antigen
- HIV 1 & 2 Antibody
- HBV Total Core Antibody
- HTLV-I & HTLV-II Antibody
- Syphilis
- HIV-I/NAT
- HCV/NAT

After consent/authorization for donation is obtained, donor history screening and laboratory testing is performed in accordance with FDA regulations and AATB Standards.

Screening for Patient Safety

A complete donor risk assessment interview must be performed for every donor including:

- Cause of death: Donors are only accepted if cause of death is established.
- Donor Risk Assessment:
  RTI receives donated tissue from independently licensed recovery agencies which screen for safety prior to recovery, including conducting an interview with the family/next of kin and a behavioral/lifestyle risk assessment.

  Following receipt of tissue from the recovery agency, RTI evaluates records from the recovery agency and performs the following donor risk assessment:
  - Medical record/hospital records review
  - Medical examiner/coroner's report (autopsy report, when available)
  - Laboratory, pathology and radiology reports

The final determination of donor eligibility is made by RTI's medical director – a licensed physician – utilizing all available, relevant information.

Testing for Patient Safety

An extensive panel of serological and microbiological tests are performed. These results are subject to stringent acceptance criteria in order to release the donor tissue.

In addition to serological testing on the donor's blood, microbiological testing is used throughout the process (where appropriate) to screen for potential contamination and to provide confirmation of tissue suitability for transplant.

BioCleanse® Tissue Sterilization Process

Bone and sports medicine soft tissue

Low temperature chemical process

BIOCLEANSE® TISSUE STERILIZATION PROCESS

Tissue sterilized to SAL 10^{-6}

Bone grafts are terminally sterilized by a validated method. Sports medicine tendons are not terminally irradiated.

Cancelle® SP DBM Sterilization Process

DBM pastes and putties

Bone undergoes demineralization

Low-temperature terminal irradiation

CANCELLE® SP DBM STERILIZATION PROCESS

Sterile finished graft

For most DBM-based implants**, the irradiation dose is applied terminally to achieve an SAL of 10^{-6}.

BioCleanse® Tissue Sterilization Process

RTI Biologics' allograft constructs/spacers and sports medicine soft tissue implants are sterilized to Sterility Assurance Level 10^{-6} through its patented BioCleanse Tissue Sterilization Process, an automated, pharmaceutical grade process. BioCleanse sterilization is used on grafts that provide a natural biologic scaffold in orthopedic, spine and sports medicine procedures.

How does the BioCleanse Process work?

The BioCleanse system sterilizes tissue to SAL 10^{-6} using a complex, proprietary combination of mechanical and chemical processes, working in conjunction with each other. The mechanical component applies oscillating positive and negative pressure in the presence of the chemical agents (including detergents and sterilants), which gently perfuse the tissue. This combination removes blood and lipids, and inactivates or removes pathogenic microorganisms. Repeated water rinses throughout the process remove debris, and final water rinses remove residual chemicals, leaving the tissue biocompatible. The BioCleanse Process does not sterilize using irradiation.

Even if other safeguards fail, RTI's BioCleanse technology sterilizes both bone and soft tissue to SAL 10^{-6}. This SAL was established using worst case testing scenarios which included Achilles tendon (because of its dense nature) and spores (because they are the most difficult microorganisms to remove).

Cancelle® SP DBM Sterilization Process

DBM pastes and putties are sterilized through the Cancelle SP Process, which is a validated bone matrix sterilization process designed to preserve protein activity. Their osteoinductive (OI) potential* is verified by 100% lot testing after sterilization. In their final form, the DBM products serve as bone void fillers in many applications, including spinal, general orthopedic and joint reconstruction surgeries.

How does the Cancelle SP Process work?

Cancelle SP is a proprietary process that sterilizes DBM while simultaneously allowing it to maintain its osteoinductive* potential. Through a combination of oxidative treatments and acid or alcohol washes, debris is removed and pathogens are inactivated. Cleansing rinses remove residual chemicals, maintaining biocompatibility, and low temperature, low dose gamma irradiation preserves the utility of the graft. For most DBM-based products**, the irradiation dose is applied terminally to achieve a sterility assurance level (SAL) of 10^{-6}.

*DBM or representative finished implant is either assayed *in vivo* in the modified athymic nude rat for bone formation or *in vitro* for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, when assayed *in vitro*, DBM is also screened for the presence of BMP-7. Findings from an *in vitro* assay or animal model are not necessarily predictive of human clinical results.

**Refer to implant package insert for specific processing information.

General Orthopedic Conventional Allografts

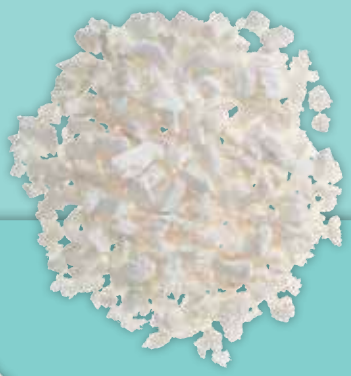
Chips and Cubes

- Sterilized through the BioCleanse® Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE

Chips and Cubes — ***Sterilization: BioCleanse®***

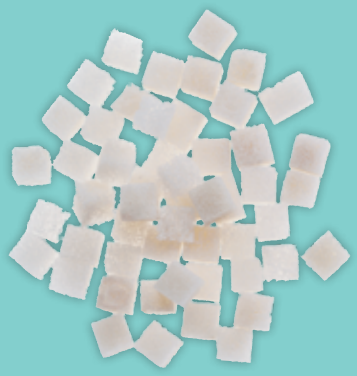
Code	Description	Preservation
	1-4mm Chips	
100005	Cancellous Chips (1-4mm) 5cc	FD
100015	Cancellous Chips (1-4mm) 15cc	FD
100030	Cancellous Chips (1-4mm) 30cc	FD
100060	Cancellous Chips (1-4mm) 60cc	FD
100090	Cancellous Chips (1-4mm) 90cc	FD
	4-10mm Chips	
100405	Cancellous Chips (4-10mm) 5cc	FD
100415	Cancellous Chips (4-10mm) 15cc	FD
100430	Cancellous Chips (4-10mm) 30cc	FD
100460	Cancellous Chips (4-10mm) 60cc	FD
100490	Cancellous Chips (4-10mm) 90cc	FD
	1-4mm Chips	
100505	Cancellous Chips (1-4mm) 5cc	FZ
100515	Cancellous Chips (1-4mm) 15cc	FZ
100530	Cancellous Chips (1-4mm) 30cc	FZ
	4-10mm Chips	
100605	Cancellous Chips (4-10mm) 5cc	FZ
100615	Cancellous Chips (4-10mm) 15cc	FZ
100630	Cancellous Chips (4-10mm) 30cc	FZ
	4-6mm Cubes	
100205	Cancellous Cubes (4-6mm) 5cc	FD
100215	Cancellous Cubes (4-6mm) 15cc	FD
100230	Cancellous Cubes (4-6mm) 30cc	FD
	6-10mm Cubes	
100305	Cancellous Cubes (6-10mm) 5cc	FD
100315	Cancellous Cubes (6-10mm) 15cc	FD
100330	Cancellous Cubes (6-10mm) 30cc	FD
	Cortical/Cancellous Blends	
110115	Cortical Cancellous Chips 40/60 MIX (1-3mm) 15cc	FD
110130	Cortical Cancellous Chips 40/60 MIX (1-3mm) 30cc	FD

FD=*Freeze Dried*

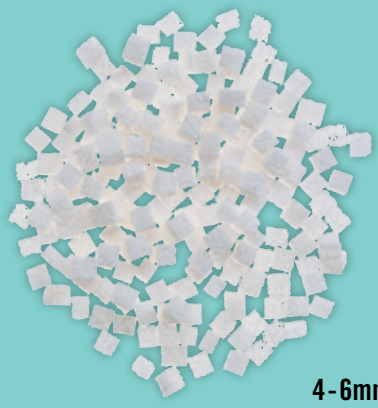


4-10mm Chips

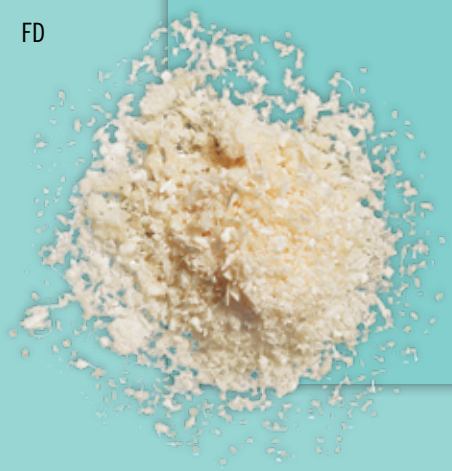
1-4mm Chips



6-10mm Cubes



4-6mm Cubes



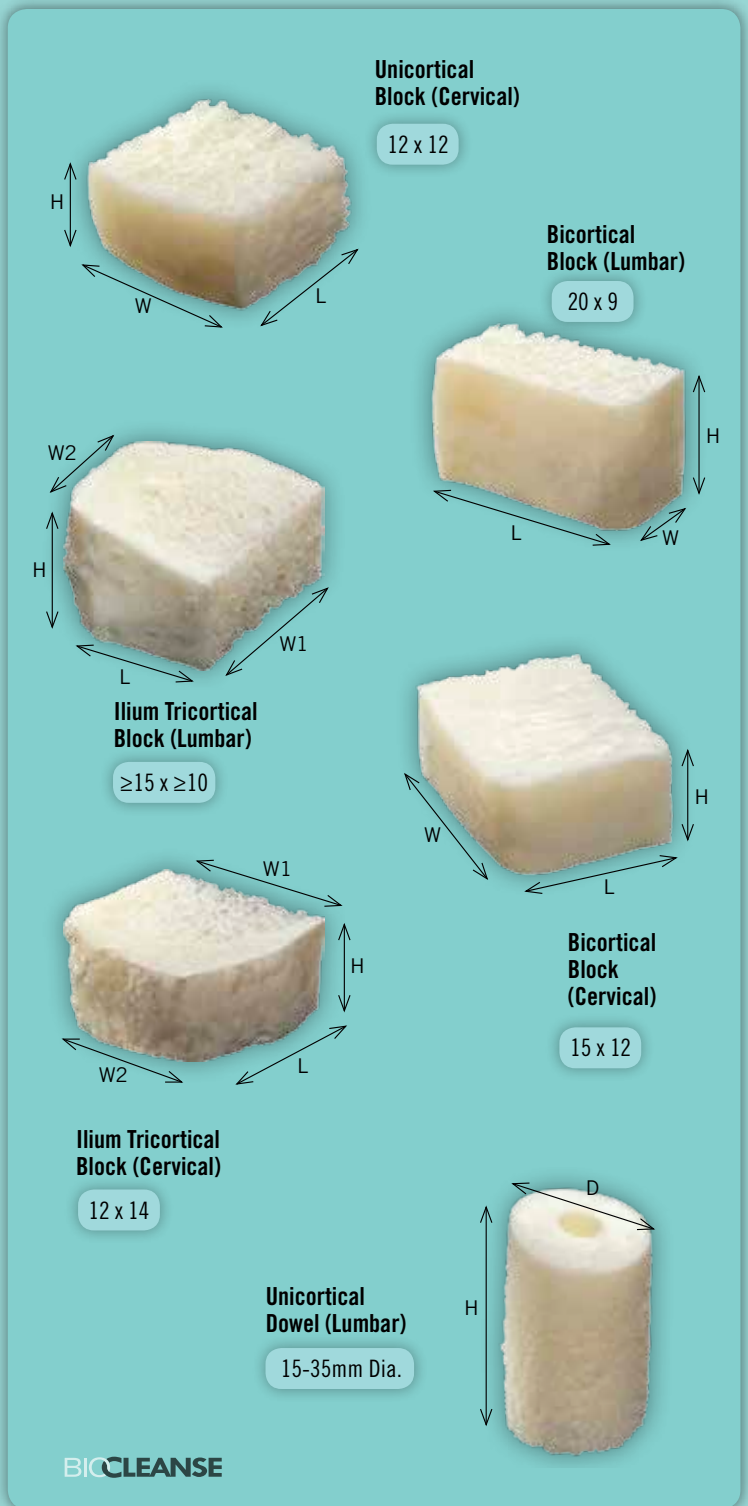
Cortical/
Cancellous Blend

BIOCLEANSE

General Orthopedic Conventional Allografts

Blocks and Dowels

- Pre-cut to select heights and footprints
- Sterilized through the BioCleanse Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE



Blocks			*Sterilization: BioCleanse®*
Code	**Description**	**H x L x W**	**Preservation**
D08562	Unicortical Block	6x12x12mm	FD
D08572	Unicortical Block	7x12x12mm	FD
D08582	Unicortical Block	8x12x12mm	FD
D08592	Unicortical Block	9x12x12mm	FD
D08502	Unicortical Block	10x12x12mm	FD
D08706	Bicortical Block	6x15x12mm	FD
D08707	Bicortical Block	7x15x12mm	FD
D08708	Bicortical Block	8x15x12mm	FD
D08709	Bicortical Block	9x15x12mm	FD
Blocks		**H x L x W**	
D08600	Bicortical Block	10x20x9mm	FD
D08602	Bicortical Block	12x20x9mm	FD
D08604	Bicortical Block	14x20x9mm	FD
D08650	Bicortical Block	10x25x9mm	FD
D08652	Bicortical Block	12x25x9mm	FD
D08654	Bicortical Block	14x25x9mm	FD
D03205	Ilium Tricortical Block	5x12x14mm	FD
D03206	Ilium Tricortical Block	6x12x14mm	FD
D03207	Ilium Tricortical Block	7x12x14mm	FD
D03208	Ilium Tricortical Block	8x12x14mm	FD
D03209	Ilium Tricortical Block	9x12x14mm	FD
D03210	Ilium Tricortical Block	10x12x14mm	FD
D03107	Ilium Tricortical Block	7x ≥15x ≥10mm	FD
D03108	Ilium Tricortical Block	8x ≥15x ≥10mm	FD
D03109	Ilium Tricortical Block	9x ≥15x ≥10mm	FD
D03110	Ilium Tricortical Block	10x ≥15x ≥10mm	FD
D03112	Ilium Tricortical Block	12x ≥15x ≥10mm	FD
D03114	Ilium Tricortical Block	14x ≥15x ≥10mm	FD
D03115	Ilium Tricortical Block	15x ≥15x ≥10mm	FD
D03116	Ilium Tricortical Block	16x ≥15x ≥10mm	FD
D03118	Ilium Tricortical Block	18x ≥15x ≥10mm	FD
D03120	Ilium Tricortical Block	20x ≥15x ≥10mm	FD
D03125	Ilium Tricortical Block	25x ≥30x ≥14mm	FD
Dowels		**H x D**	
D02812	Unicortical Dowel	12x15-35mm	FD
D02814	Unicortical Dowel	14x15-35mm	FD
D02816	Unicortical Dowel	16x15-35mm	FD
D02818	Unicortical Dowel	18x15-35mm	FD

General Orthopedic Conventional Allografts

Wedges

- Sterilized through the BioCleanse® Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE

Measurements Recorded:
- Maximum length ≥ 50mm
- Maximum height
- Minimum width ≥ 40mm

Angle measured on small end

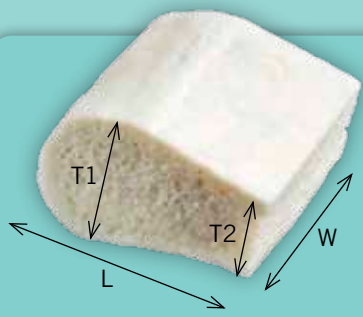
BIOCLEANSE

HTO Wedge ***Sterilization: BioCleanse®***

Code	Description (Height)	Preservation
180672	HTO Wedge 6 degrees, 7.5mm	FD
180872	HTO Wedge 8 degrees, 10.0mm	FD
181072	HTO Wedge 10 degrees, 12.5mm	FD
181272	HTO Wedge 12 degrees, 15.0mm	FD
181472	HTO Wedge 14 degrees, 17.5mm	FD
190672	HTO Wedge 6 degrees, 7.5mm	FZ
190872	HTO Wedge 8 degrees, 10.0mm	FZ
191072	HTO Wedge 10 degrees, 12.5mm	FZ
191272	HTO Wedge 12 degrees, 15.0mm	FZ
191472	HTO Wedge 14 degrees, 17.5mm	FZ

Strips

- Sterilized through the BioCleanse® Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE



Measurements Recorded:
- Maximum width
- Minimum length >24mm
- Maximum thickness >9mm
- Minimum thickness

BIOCLEANSE

Ilium Tricortical Strip ***Sterilization: BioCleanse®***

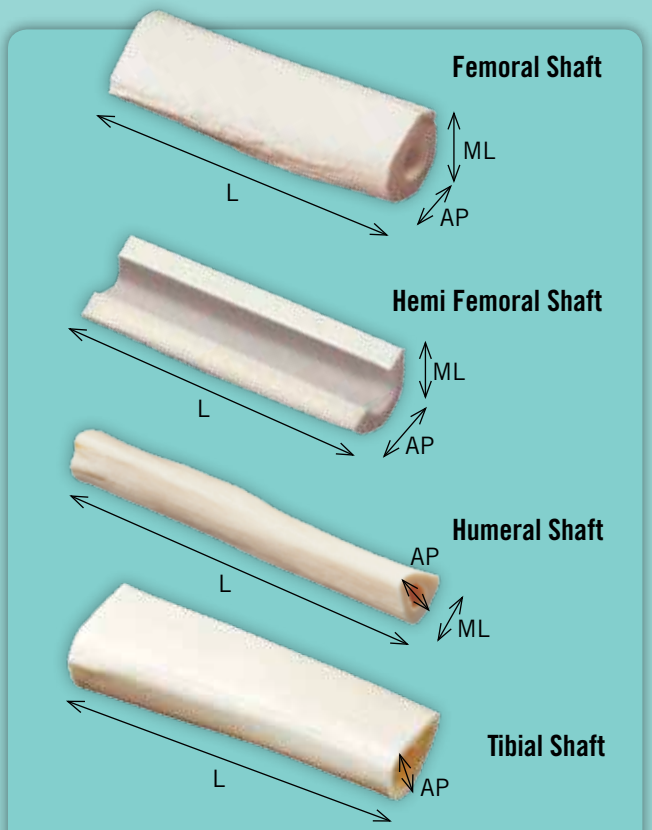
Code	Description (Width)	Preservation
339030	Ilium Strip Tricortical 28-45mm	FZ
339050	Ilium Strip Tricortical 46-57mm	FZ
339060	Ilium Strip Tricortical >58mm	FZ
330030	Ilium Strip Tricortical 28-45mm	FD
330050	Ilium Strip Tricortical 46-57mm	FD
330060	Ilium Strip Tricortical >58mm	FD

FD=*Freeze Dried*
FZ=*Frozen*

General Orthopedic Conventional Allografts

Shafts

- Pre-cut to select lengths to reduce OR prep time
- Sterilized through the BioCleanse Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE



Measurements Recorded:
- Length
- AP diameter and ML diameter

Minimum cortical-wall thickness of 3mm

BIOCLEANSE

Femoral Shafts — ***Sterilization: BioCleanse®***

Code	Description (Length)	Preservation
639010	Femoral Shaft 98-130mm	FZ
639015	Femoral Shaft 131-165mm	FZ
639020	Femoral Shaft 166-202mm	FZ
632010	Femoral Shaft 98-130mm	FD
632015	Femoral Shaft 131-165mm	FD
632020	Femoral Shaft 166-202mm	FD
Hemi Femoral Shafts		
639110	Hemi Femoral Shaft 98mm-130mm	FZ
639115	Hemi Femoral Shaft 131mm-165mm	FZ
639120	Hemi Femoral Shaft 166mm-202mm	FZ
632110	Hemi Femoral Shaft 98mm-130mm	FD
632115	Hemi Femoral Shaft 131mm-165mm	FD
632120	Hemi Femoral Shaft 166mm-202mm	FD
Humeral Shafts		
699060	Humeral Shaft 50mm-100mm	FZ
699010	Humeral Shaft 101mm-150mm	FZ
691060	Humeral Shaft 50mm-100mm	FD
692010	Humeral Shaft 101mm-150mm	FD
Tibial Shafts		
789060	Tibial Shaft 50mm-75mm	FZ
789010	Tibial Shaft 76mm-102mm	FZ
789015	Tibial Shaft 103mm-152mm	FZ
781060	Tibial Shaft 50mm-75mm	FD
782010	Tibial Shaft 76mm-102mm	FD
782015	Tibial Shaft 103mm-152mm	FD

Measurements Recorded:
- Length
- AP diameter and ML diameter

Minimum cortical-wall thickness of 1.5mm

BIOCLEANSE

Fibula Shafts — ***Sterilization: BioCleanse®***

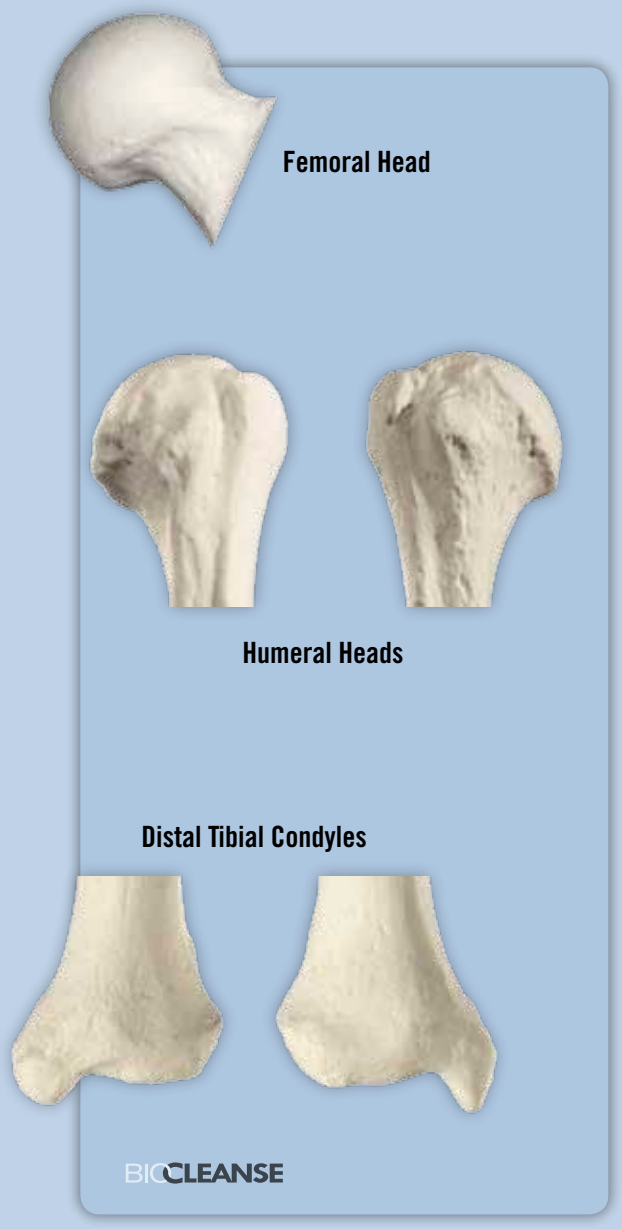
Code	Description (Length)	Preservation
669060	Fibula Shaft 50mm-75mm	FZ
669080	Fibula Shaft 76mm-98mm	FZ
669010	Fibula Shaft 99mm-125mm	FZ
661060	Fibula Shaft 50mm-75mm	FD
661080	Fibula Shaft 76mm-98mm	FD
662010	Fibula Shaft 99mm-125mm	FD

FD=*Freeze Dried*
FZ=*Frozen*

Reconstructive Large Segmental Allografts

Heads and Condyles

- Existing cartilage still attached (except femoral head)
- Sterilized through the BioCleanse® Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE



Femoral Head

Sterilization: BioCleanse®

Code	Description	Preservation
620100	Femoral Head w/o Cartilage	FZ

Humeral Head

Left	Right	Description	Preservation
680001	680002	Humeral Head	FZ

Distal Tibial Condyle

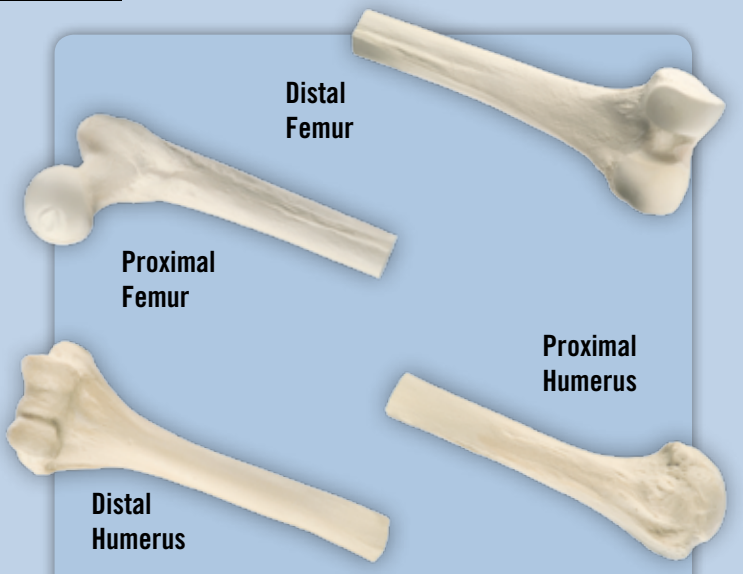
Left	Right	Description	Preservation
770301	770302	Distal Tibial Condyle	FZ

FZ=*Frozen*

Reconstructive Large Segmental Allografts

Proximal and Distal Grafts

- Existing cartilage still attached
- Sterilized through the BioCleanse Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE



Femur — *Sterilization: BioCleanse®*

Left	Right	Description	Length	Preservation
640207	640208	Distal Femur Short	150-250mm	FZ
640217	640218	Distal Femur Long	251-350mm	FZ
640107	640108	Proximal Femur Short	150-250mm	FZ
640117	640118	Proximal Femur Long	251-350mm	FZ

Humerus

Left	Right	Description	Length	Preservation
670101	670102	Proximal Humerus Short	130-200mm	FZ
670111	670112	Proximal Humerus Long	201-270mm	FZ
670201	670202	Distal Humerus Short	130-200mm	FZ
670211	670212	Distal Humerus Long	201-270mm	FZ

Tibia

Left	Right	Description	Length	Preservation
760201	760202	Distal Tibia Short	150-200mm	FZ
760211	760212	Distal Tibia Long	201-300mm	FZ
760101	760102	Proximal Tibia Short	150-200mm	FZ
760111	760112	Proximal Tibia Long	201-300mm	FZ

BIOCLEANSE

Measurements Recorded:

Distal Femur
- Length
- ML measurement of distal condyle
- AP measurement of distal condyle
- Shaft's outer diameter
- Cortical-wall thickness

Proximal Femur w/Head
- Length
- Femoral head outer diameter
- Shaft's outer diameter
- Cortical-wall thickness

Proximal Humerus
- Length
- Shaft's outer diameter
- Cortical-wall thickness
- Proximal condyle's outer diameter

Distal Humerus
- Length
- Shaft's outer diameter
- Cortical-wall thickness

BIOCLEANSE

Measurements Recorded:

Distal Tibia
- Length
- ML measurement of distal condyle
- AP measurement of distal condyle
- Shaft's outer diameter
- Cortical-wall thickness

Proximal Tibia
- Length
- ML measurement of proximal condyle
- AP measurement of proximal condyle
- Shaft's outer diameter
- Cortical-wall thickness

FZ=*Frozen*

Reconstructive Large Segmental Allografts

Whole Bones

- Existing cartilage still attached
- Sterilized through the BioCleanse® Process
- Terminal sterilization after the BioCleanse Process achieves SAL 10^{-6} and labeled STERILE

Femur

Sterilization: BioCleanse®

Left	Right	Description	Length	Preservation
640001	640002	Whole Femur	Variable	FZ

Humerus

Left	Right	Description	Length	Preservation
670001	670002	Whole Humerus	Variable	FZ

Tibia

Left	Right	Description	Length	Preservation
760001	760002	Whole Tibia	Variable	FZ

Fibula

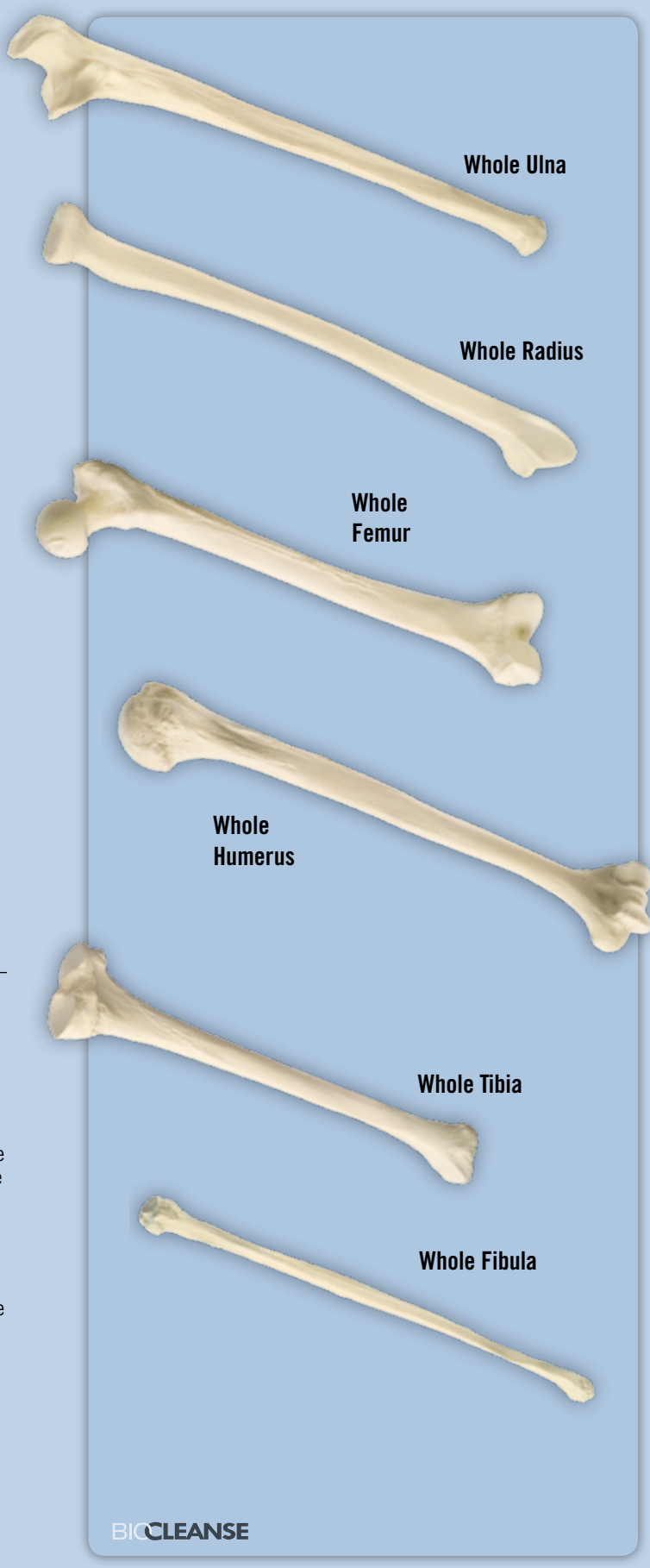
Left	Right	Description	Length	Preservation
650001	650002	Whole Fibula	Variable	FZ

Radius

Left	Right	Description	Length	Preservation
730001	730002	Whole Radius	Variable	FZ

Ulna

Left	Right	Description	Length	Preservation
790001	790002	Whole Ulna	Variable	FZ



Measurements Recorded:

Whole Ulna
- Length
- ML measurement of proximal condyle
- AP measurement of proximal condyle
- Shaft's outer diameter
- ML measurement of distal condyle
- AP measurement of distal condyle

Whole Radius
- Length
- ML measurement of proximal condyle
- ML measurement of distal condyle
- Shaft's outer diameter

Whole Femur
- Length
- ML measurement of distal condyle
- Shaft's outer diameter
- Femoral head outer diameter
- AP measurement of distal condyle

Whole Humerus
- Length
- Shaft's outer diameter
- Proximal head outer diameter

Whole Tibia
- Length
- ML measurement of proximal condyle
- AP measurement of proximal condyle
- Shaft's outer diameter
- ML measurement of distal condyle

Whole Fibula
- Length
- ML measurement of proximal condyle
- ML measurement of distal condyle
- Shaft's outer diameter

FZ=*Frozen*

Osteoinductive Demineralized Bone Grafts

DBM Powder

- Osteoinductive* (OI) potential is verified by 100% lot testing after sterilization
- Sterilized through the Cancelle® SP DBM Sterilization Process using low-temperature, low dose gamma irradiation to achieve SAL 10^{-6}

DBM Powder — ***Sterilization: Cancelle® SP***

Code	Description	Preservation
004805	DBM Powder 5cc	FD
004810	DBM Powder 10cc	FD
004815	DBM Powder 15cc	FD

FD=*Freeze Dried*

BioReady™ DBM Putty

- Ready-to-use, 100% allograft
- Pliable without becoming hard or setting
- Osteoinductive* (OI) potential is verified by 100% lot testing after sterilization
- Sterilized through the Cancelle® SP DBM Sterilization Process using low-temperature, low dose gamma irradiation to achieve SAL 10^{-6}

Putty — ***Sterilization: Cancelle® SP***

Code	Description	Preservation
D00100	BioReady™ DBM Putty 0.5cc	Pre-hydrated
D00101	BioReady™ DBM Putty 1cc	Pre-hydrated
D00102	BioReady™ DBM Putty 2cc	Pre-hydrated
D00105	BioReady™ DBM Putty 5cc	Pre-hydrated
D00110	BioReady™ DBM Putty 10cc	Pre-hydrated

Putty with Chips

Code	Description	Preservation
D00300	BioReady™ DBM Putty with Chips 0.5cc	Pre-hydrated
D00301	BioReady™ DBM Putty with Chips 1cc	Pre-hydrated
D00302	BioReady™ DBM Putty with Chips 2cc	Pre-hydrated
D00305	BioReady™ DBM Putty with Chips 5cc	Pre-hydrated
D00310	BioReady™ DBM Putty with Chips 10cc	Pre-hydrated
D00320	BioReady™ DBM Putty with Chips 20cc	Pre-hydrated

*DBM or representative finished implant is either assayed *in vivo* in the modified athymic nude rat for bone formation or *in vitro* for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, when assayed *in vitro*, DBM is also screened for the presence of BMP-7. Findings from an *in vitro* assay or animal model are not necessarily predictive of human clinical results.

Osteoinductive Demineralized Bone Grafts

BioSet® DBM Allograft Paste

- Can be hydrated with fluid of choice
- Sets once implanted
- Osteoinductive* (OI) potential is verified by 100% lot testing after sterilization
- Sterilized through the Cancelle® SP DBM Sterilization Process using low-temperature, low dose gamma irradiation to achieve SAL 10^{-6}

BioSet® DBM Allograft Paste — ***Sterilization: Cancelle® SP***

Code	Description	Preservation
005700	BioSet® RT Allograft Paste, Syringe, 0.5cc	DR
005701	BioSet® RT Allograft Paste, Syringe, 1cc	DR
005705	BioSet® RT Allograft Paste, Syringe, 5cc	DR
005710	BioSet® RT Allograft Paste, Syringe, 10cc	DR
005800	BioSet® Allograft Paste, Syringe, 0.5cc	FZ
005801	BioSet® Allograft Paste, Syringe, 1cc	FZ
005805	BioSet® Allograft Paste, Syringe, 5cc	FZ
005810	BioSet® Allograft Paste, Syringe, 10cc	FZ
006702	BioSet® IC, RT Allograft Paste, 2cc	DR
006705	BioSet® IC, RT Allograft Paste, 5cc	DR
006710	BioSet® IC, RT Allograft Paste, 10cc	DR
006720	BioSet® IC, RT Allograft Paste, 20cc	DR
006805	BioSet® IC Moldable Allograft Paste, Syringe, 5cc	FZ
006810	BioSet® IC Moldable Allograft Paste, Syringe, 10cc	FZ
006820	BioSet® IC Moldable Allograft Paste, Syringe, 20cc	FZ
007820	BioSet® IC Allograft Full Disc, 20 x 3mm, 1cc	FZ
007890	BioSet® IC Allograft Full Disc, 90 x 5mm, 32cc	FZ
007830	BioSet® IC Allograft Full Disc, 30 x 3mm, 2cc	FZ
007845	BioSet® IC Allograft Full Disc, 45 x 5mm, 5cc	FZ
007875	BioSet® IC Allograft Partial Disc, 75 x 5mm, 15cc	FZ
007891	BioSet® IC Allograft Partial Disc, 90 x 5mm, 22cc	FZ
008850	BioSet® IC Moldable Strip, 50mm (2 each), 6cc	FZ
008890	BioSet® IC Moldable Strip, 90mm (2 each), 10cc	FZ

DR=*Dried*
FZ=*Frozen*

*These products induced bone formation when evaluated using the modified athymic nude rat assay. Findings from an animal model are not necessarily predictive of human clinical results.

Osteoinductive Demineralized Bone Grafts

BioAdapt™ Foam

- Can be hydrated with fluid of choice
- Pre-shaped DBM that expands with hydration to provide a contoured fit to the bony defect
- Osteoinductive* (OI) potential is verified by 100% lot testing after sterilization
- Sterilized through the BioCleanse® Process and Cancelle® SP DBM Sterilization Process using low-temperature, low dose gamma irradiation to achieve SAL 10^{-6}

*DBM or representative finished implant is either assayed *in vivo* in the modified athymic nude rat for bone formation or *in vitro* for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, when assayed *in vitro*, DBM is also screened for the presence of BMP-7. Findings from an *in vitro* assay or animal model are not necessarily predictive of human clinical results.

BioAdapt™ Foam — ***Sterilization: BioCleanse®, Cancelle® SP***

Code	Description	L x W x H, Volume	Preservation
DU0110	BioAdapt™ Foam, Skinny Strips	100 x 10 x 8mm, 16cc	DR
DU0125	BioAdapt™ Foam, Large Strip	100 x 25 x 5mm, 12cc	DR
DU0025	BioAdapt™ Foam, Medium Strip	50 x 25 x 5mm, 6cc	DR
DU0015	BioAdapt™ Foam, Small Strip	15 x 15 x 8mm, 2cc	DR
DU0060	BioAdapt™ Foam, Disc	60 (diam.) x 5mm, 14cc	DR

Precision Machined Spine Spacers

Cortical Cervical Spacer

- Available in 12x14mm (small) and 14x16mm (large) footprints
- Available in parallel and lordotic (7°) profiles
- Sterilized through the BioCleanse® Process
- Terminal Sterilization after BioCleanse achieves SAL 10^{-6} and labeled STERILE

12mm (AP) x 14mm (ML) — ***Sterilization: BioCleanse®***

Code	Description	Preservation
D0P146	Cortical Cervical Spacer, Parallel - Small 6mm	FD
D0P147	Cortical Cervical Spacer, Parallel - Small 7mm	FD
D0P148	Cortical Cervical Spacer, Parallel - Small 8mm	FD
D0P149	Cortical Cervical Spacer, Parallel - Small 9mm	FD
D0P140	Cortical Cervical Spacer, Parallel - Small 10mm	FD
D0L146	Cortical Cervical Spacer, Lordotic - Small 6mm	FD
D0L147	Cortical Cervical Spacer, Lordotic - Small 7mm	FD
D0L148	Cortical Cervical Spacer, Lordotic - Small 8mm	FD
D0L149	Cortical Cervical Spacer, Lordotic - Small 9mm	FD
D0L140	Cortical Cervical Spacer, Lordotic - Small 10mm	FD

14mm (AP) x 16mm (ML)

Code	Description	Preservation
D0P166	Cortical Cervical Spacer, Parallel - Large 6mm	FD
D0P167	Cortical Cervical Spacer, Parallel - Large 7mm	FD
D0P168	Cortical Cervical Spacer, Parallel - Large 8mm	FD
D0P169	Cortical Cervical Spacer, Parallel - Large 9mm	FD
D0P160	Cortical Cervical Spacer, Parallel - Large 10mm	FD
D0L166	Cortical Cervical Spacer, Lordotic - Large 6mm	FD
D0L167	Cortical Cervical Spacer, Lordotic - Large 7mm	FD
D0L168	Cortical Cervical Spacer, Lordotic - Large 8mm	FD
D0L169	Cortical Cervical Spacer, Lordotic - Large 9mm	FD
D0L160	Cortical Cervical Spacer, Lordotic - Large 10mm	FD

DR=*Dried*
FD=*Freeze Dried*

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