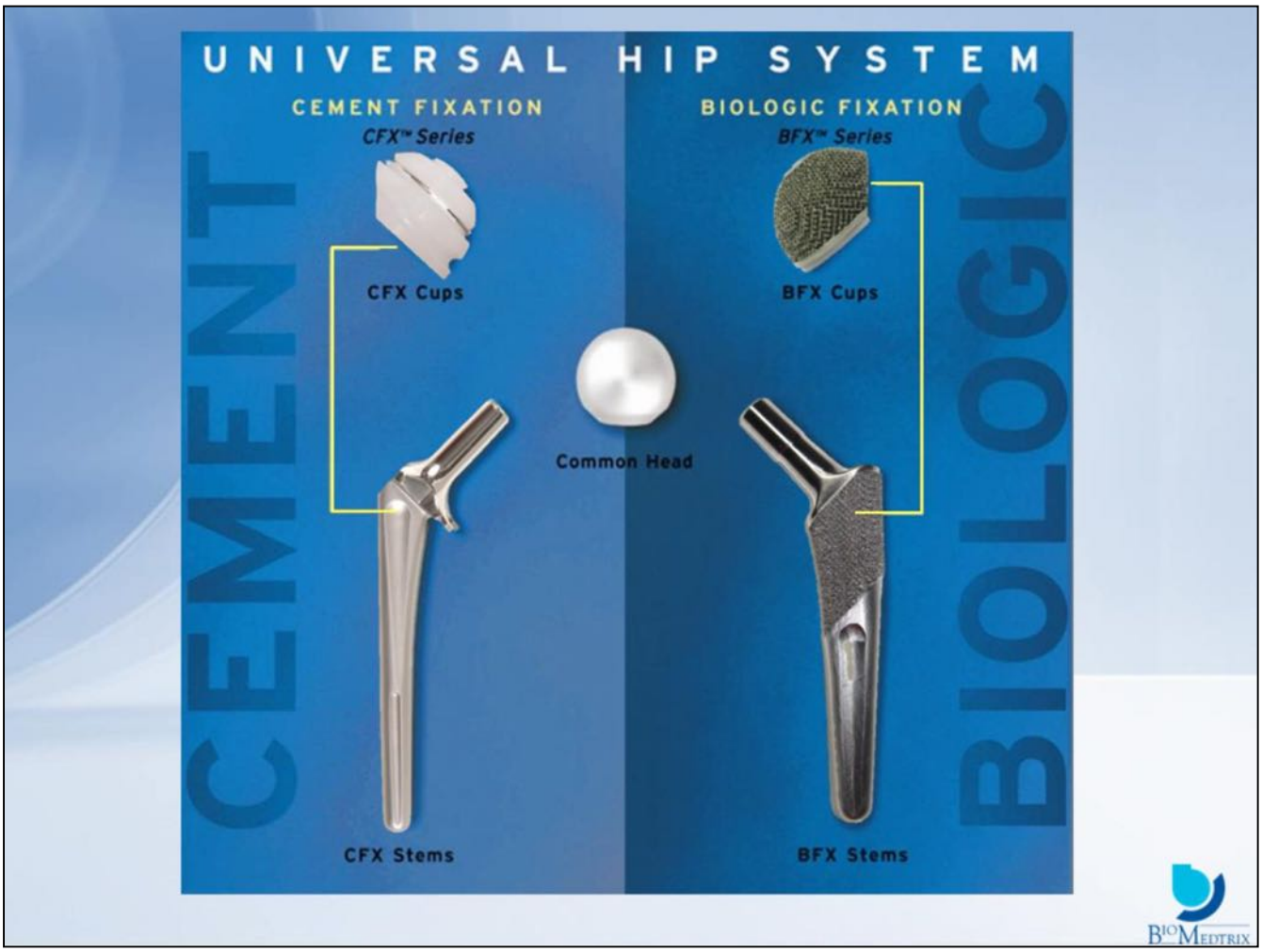


This talk reviews the Universal Hip System: composed of the CFX hip series, for cemented applications and the BFX hip series, for cementless hip applications.

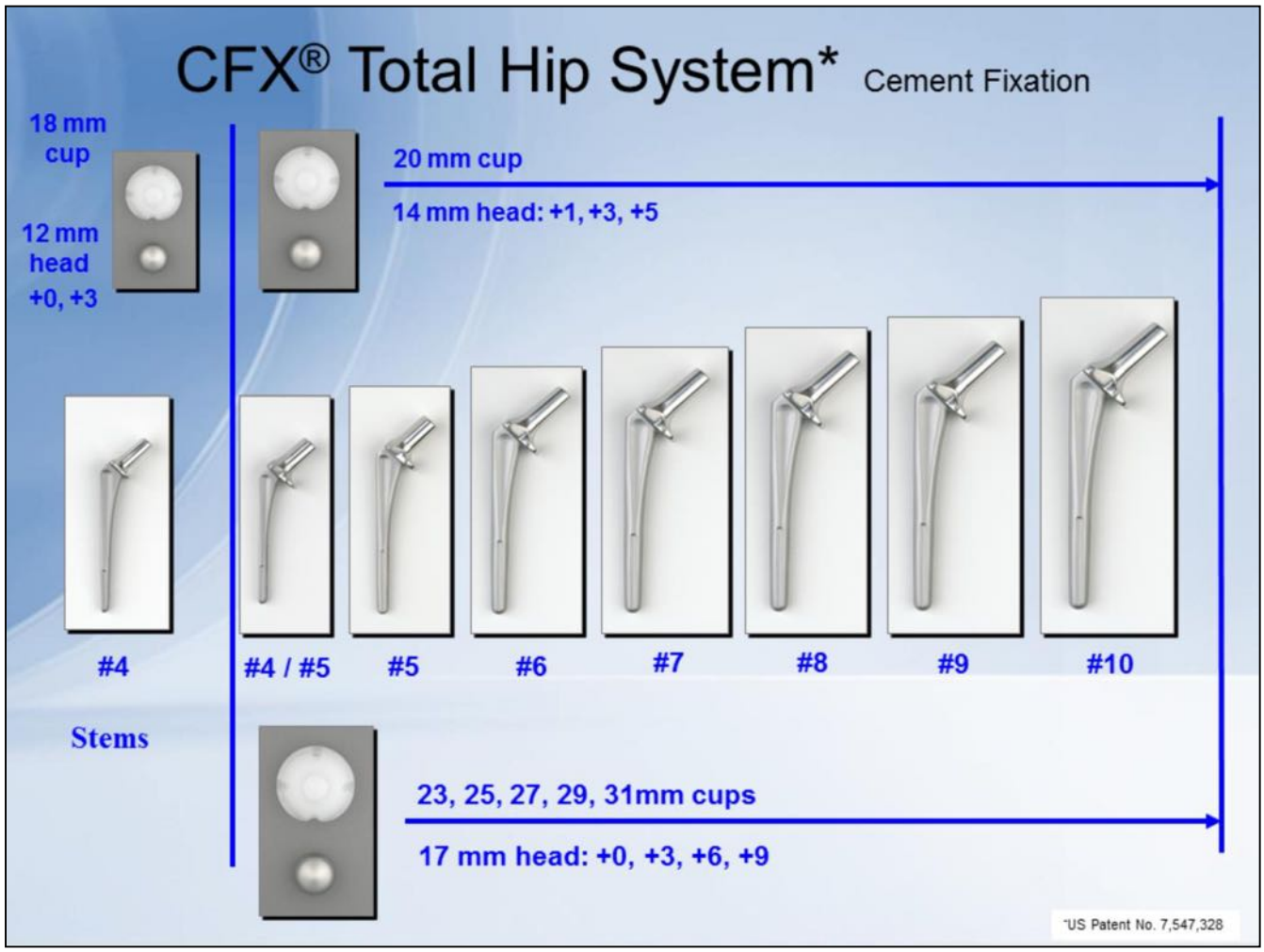
Both systems share a common surgical procedure and

Also share a common 17mm head.

This provides interchangeability between systems so BFX components can be used with CFX components expanding the clinical indications for the system.

CFX portion of the Universal Hip System has also been expanded for Micro and Nano breed dogs and cats.

There is a single set of instruments which accommodates both implant series.



We will start with a system overview of the CFX hip series.

There are 8 stems, and 7 cups.

All other components are interchangeable except the #4 stem which can only be coupled with 18mm cup.

This system was developed in 1989 with Dr. Marvin Olmstead who was a professor at the Ohio State University at that time.

The first clinical case was performed in June 1990.

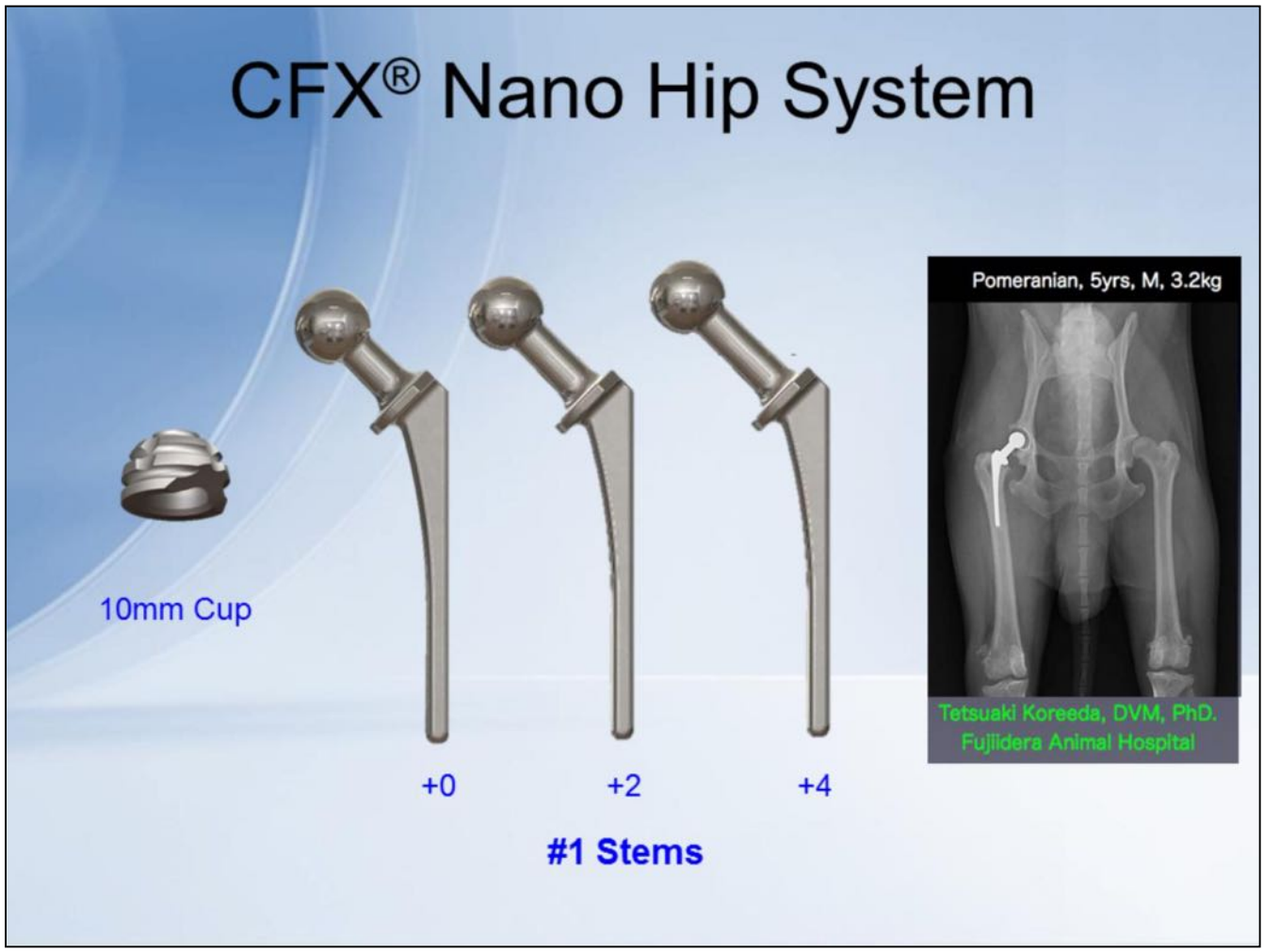
The CFX series was expanded in 2005 with Micro Implants.

These implants were design to address hip dysplasia and osteoarthritis in cats and micro breed dogs.

The first case was performed in 2000 as a custom implant.

Further custom cases were performed between 2000 and 2004 with successful results.

This lead to introduction in May 2005 with clinical assistance from Dr. Bill Liska.

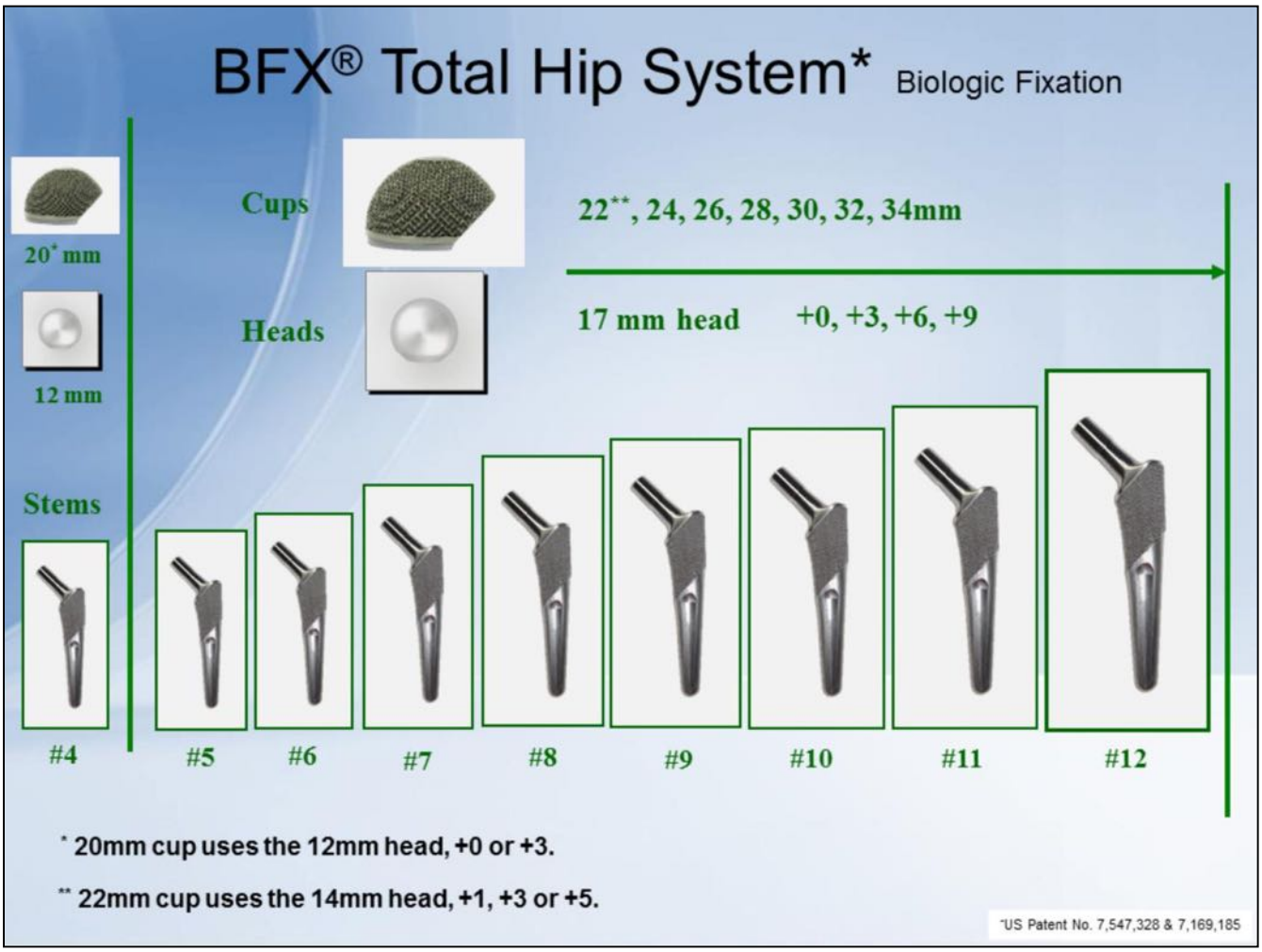


There are several studies conducted on FHO which have indicated that Total Hip Replacement (THR) provides improved pain-free function.

This lead to development of the #1 CFX stem in three (3) neck lengths. Due to the size of the head (6mm), it was more appropriate from a functional aspect to design the stem as a monoblock stem—head and stem connected.

These stems mate with a 10mm cup (6mm ID).

The system was introduced in a similar manner through custom cases with Dr. Bill Liska and Dr. Dominic Marino. The Nano hip series was introduced as a standard product in February 2010.

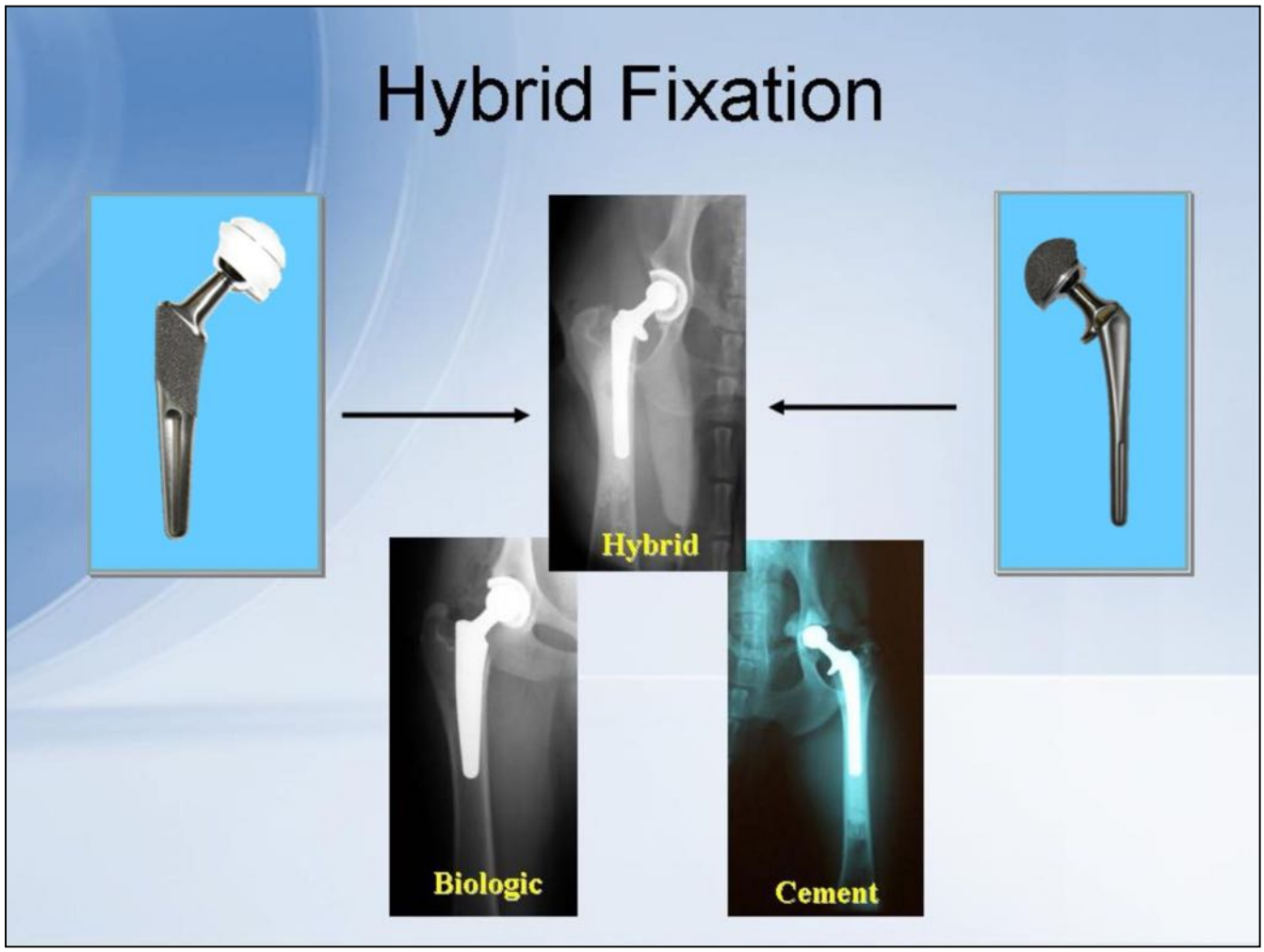


The BFX series has 9 stems and 8 cups.

These implants were developed in conjunction with Dr. Dave DeYoung, assistant dean of NC State University and later Dean of Ross University.

All components are intended for cementless hip applications.

All components are interchangeable with exception of the #4 stem which can only be used with the 20mm acetabular cup.



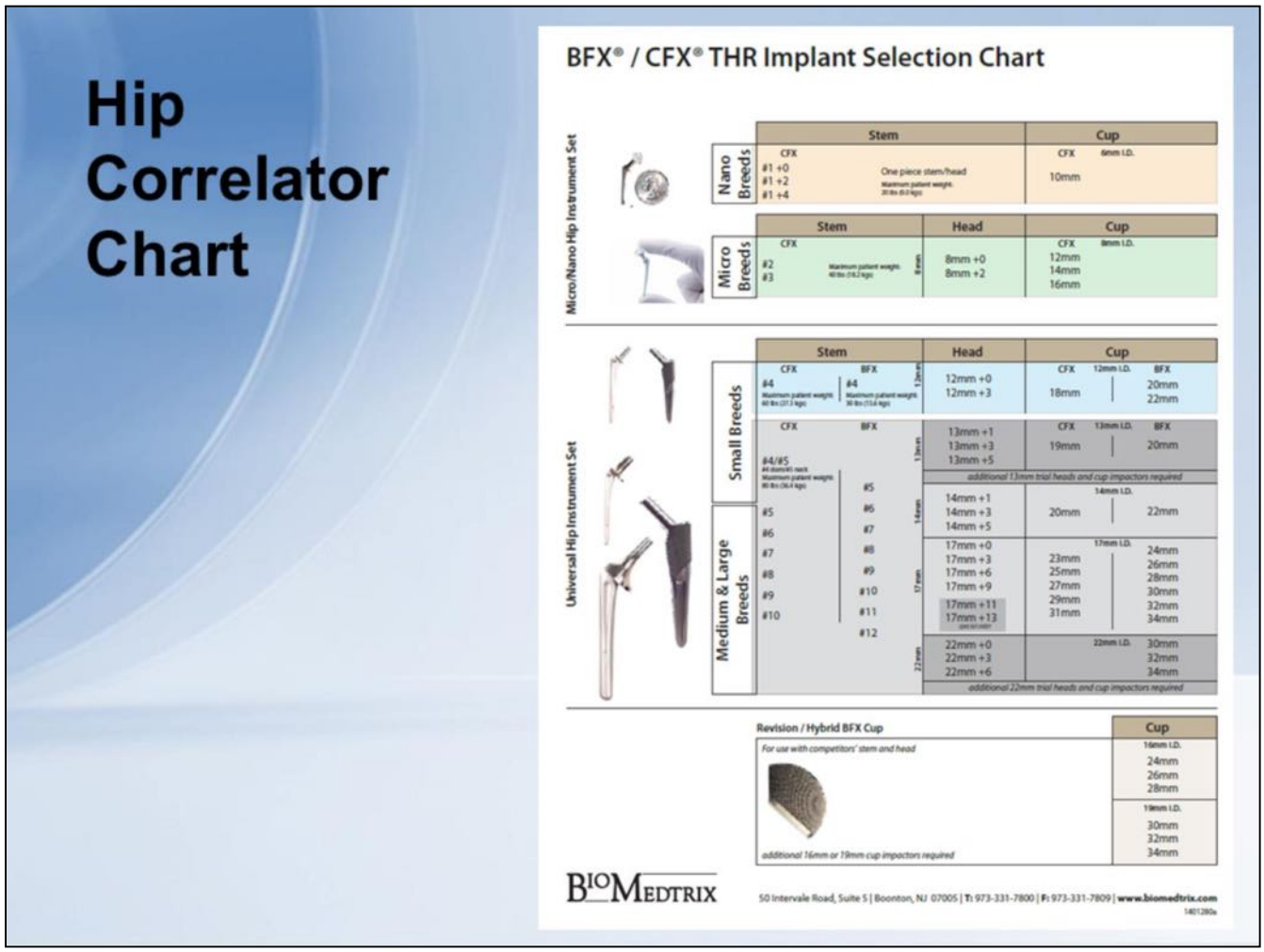
Besides matched implant combinations within each system, it is possible to have hybrid fixation.

Hybrid fixation is a combination of a cemented application on one side of the joint and cementless on the other.

For example, there are clinical indications which are best addressed with a cemented stem and press fit cup.

We will discuss this further, but some of the larger breeds (Great Danes) and other breeds like German Shepherds do not have femoral canal geometry adequate to achieve a press fit or the quality of the cancellous bone is not adequate to support a cementless stem. In those cases, the more appropriate clinical option is hybrid fixation.

Hip Correlator Chart

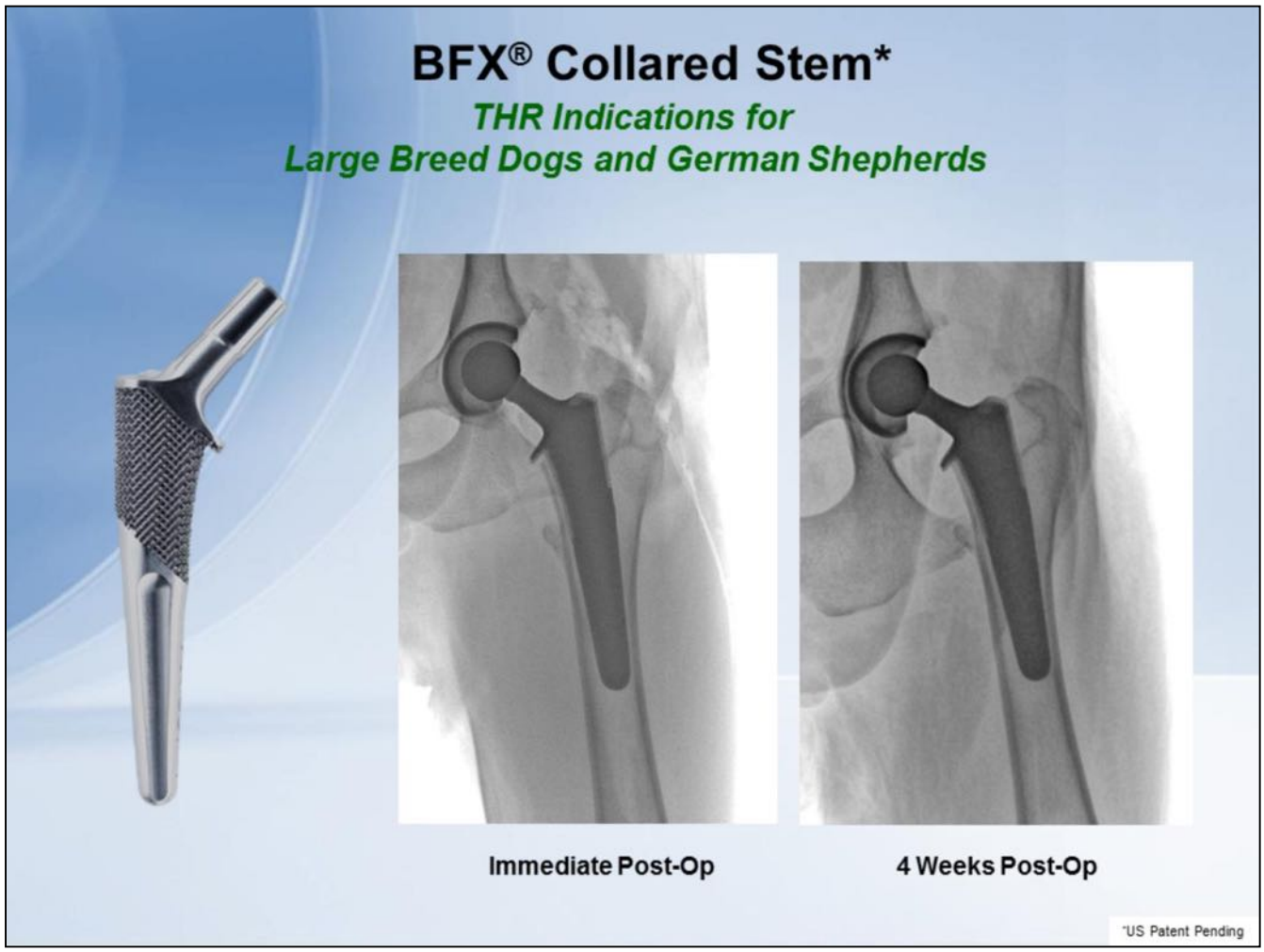


There are many implant choices with these systems. A correlator chart was developed as a quick reference to determining available implant combinations.

If a particular stem has been sized for a patient's femur, then that size can be referenced and all implant combinations are shown for the acetabular side.

The same holds true for sizing the acetabular cup first.

This chart is provided as part of the welcome package sent to all workshop registrants.



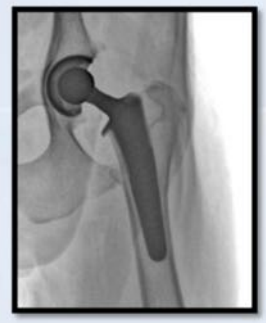
Additions to the Universal Hip System include the BFX Collared Stem.

The first case was performed on 11-01-11 as a custom with Dr. Bill Liska.

Dr. Liska has extensive clinical follow-up and routinely uses the collared stem as a standard product providing additional resistance to stem subsidence.

ASTM F-136 (Wrought Titanium Alloy 6Al-4V)

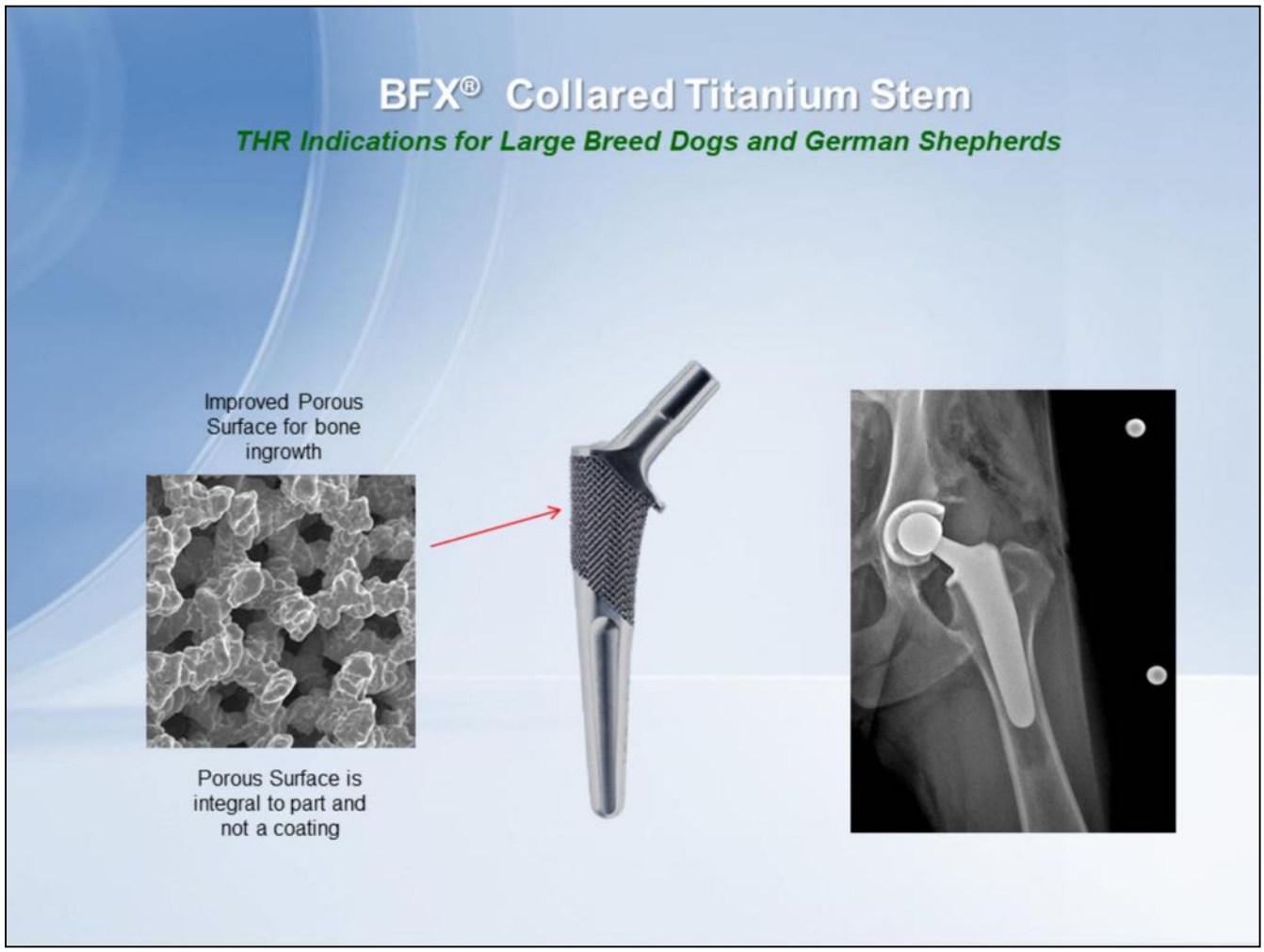
- BFX® Titanium Stems use the **same Universal Hip Instrumentation and same surgical technique** as the beaded cobalt chrome stems.
- **EBM** (Electron Beam Melting) is an FDA approved manufacturing process capable of creating one-piece implants (no additional coating for ingrowth) with optimum mechanical properties.
- **Clinical indications** for the collared stem are large breed dogs, German Shepherds and dogs with a low canal flare index (*"stove pipe" geometry*).
- Collar is designed to **resist subsidence** and assist in stabilizing the stem for bone ingrowth in the early post-op period.
- Titanium alloy provides **improved biocompatibility** and is the preferred material for human hip stems.
- Cranial and caudal flutes provide **improved stem insertion**.
- Bone attachment is through the proximal fully interconnected **3-D titanium structure**.
- Porous surface has **increased coefficient of friction** for improved resistance to subsidence.



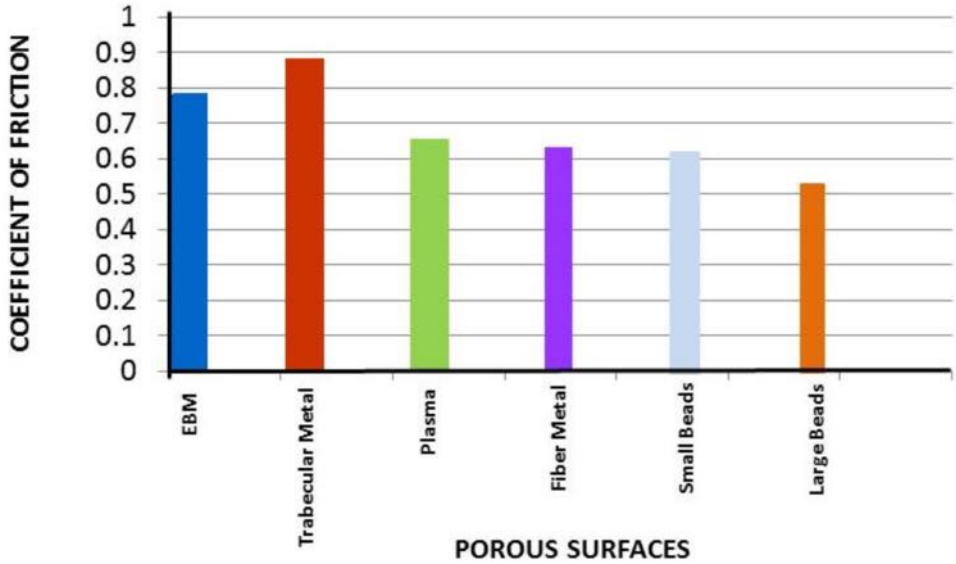
BFX Ti Collared Stem

Description	Part No.
Ti Collared Stem #6	10-202-6
Ti Collared Stem #7	10-202-7
Ti Collared Stem #8	10-202-8
Ti Collared Stem #9	10-202-9
Ti Collared Stem #10	10-202-10
Ti Collared Stem #11	10-202-11
Ti Collared Stem #12	10-202-12

Specific design features are listed on this slide explaining potential improvements of the BFX Collared Stem.

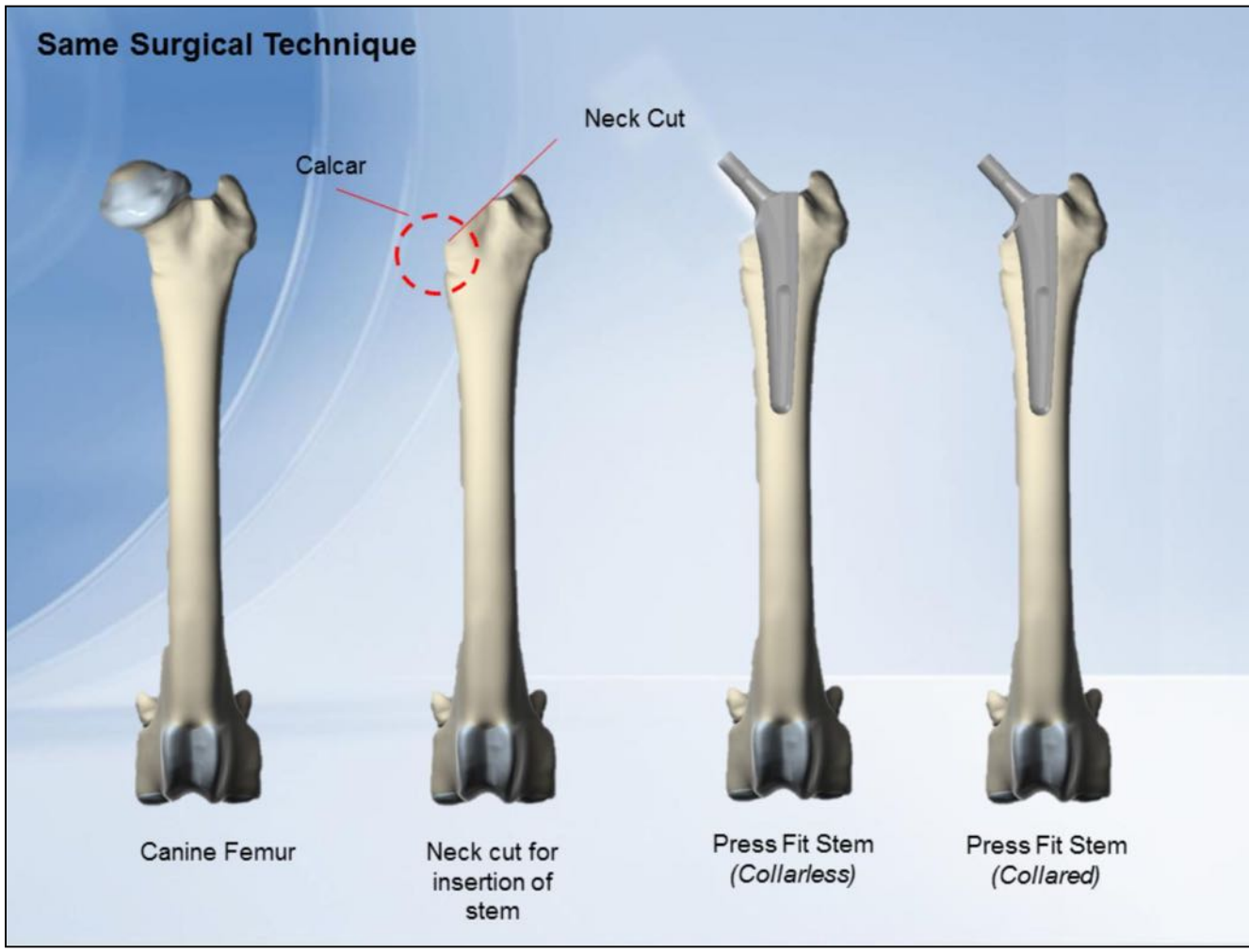


EBM (Electron Beam Melting) is an FDA approved manufacturing process capable of creating one-piece implants (no additional coating for ingrowth) with optimum mechanical properties.

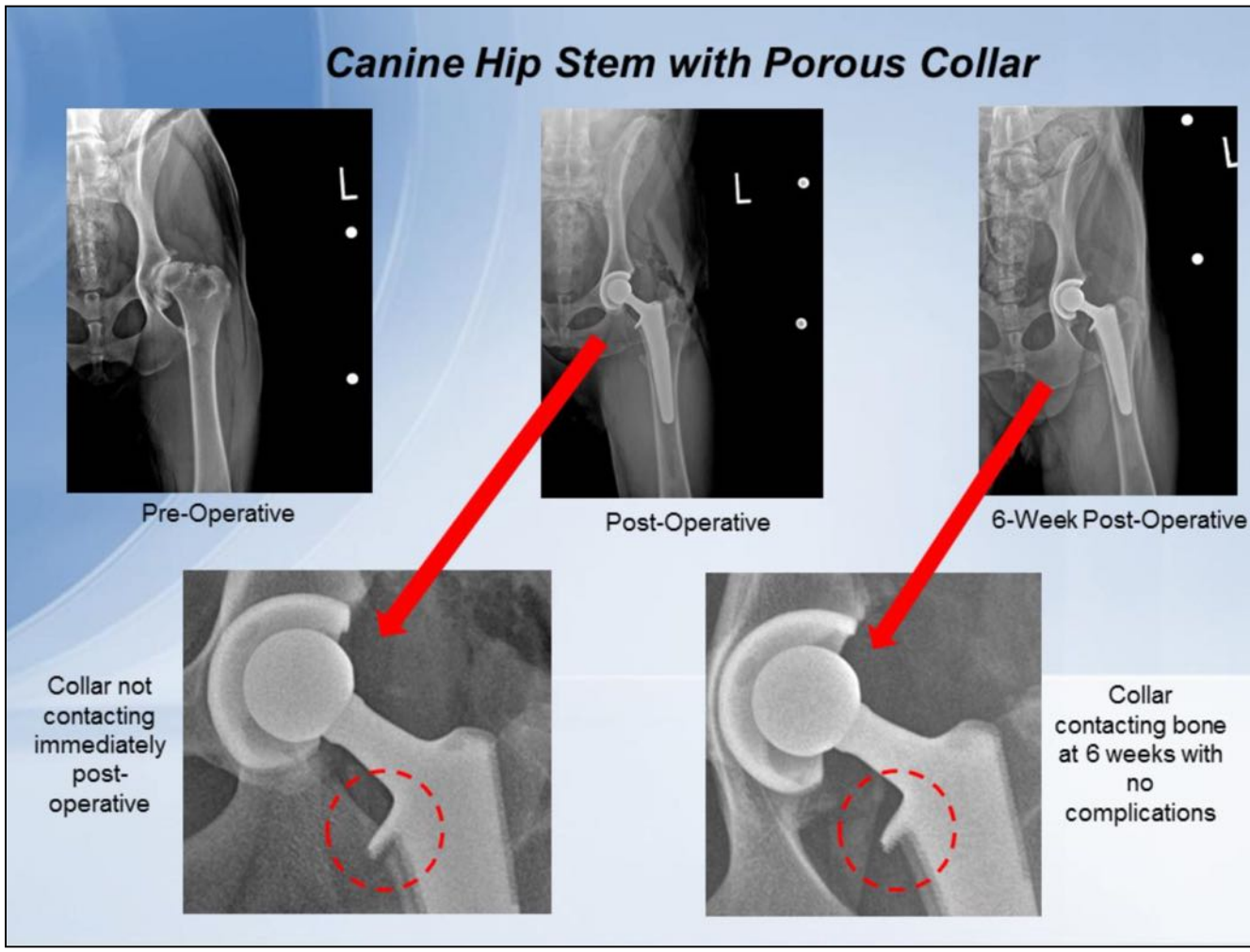


1. Tom Brown, Ph.D. et.al.: Interfacial Frictional Behavior: Cancellous Bone, Cortical Bone and a Novel Porous Tantalum Biomaterial. J. Musculoskeletal Research. Vol. 3, Issue 04, December 1999.
2. J.E. Biemond, et.al.: Frictional and bone ingrowth properties of engineered surface topographies produced by electron beam technology. Acta Ortho Trauma Surg vol. 131:711-718 (2011).
3. Internal technical report: Limacorporate S.p.a. – Via Nazionale n. 52, 33038 Villanova di San Daniele del Friuli (Udine, Italia). P.IVA: 01427710304. Codice fiscale e N.ro iscrizione al Registro delle Imprese di Udine: 0142771030

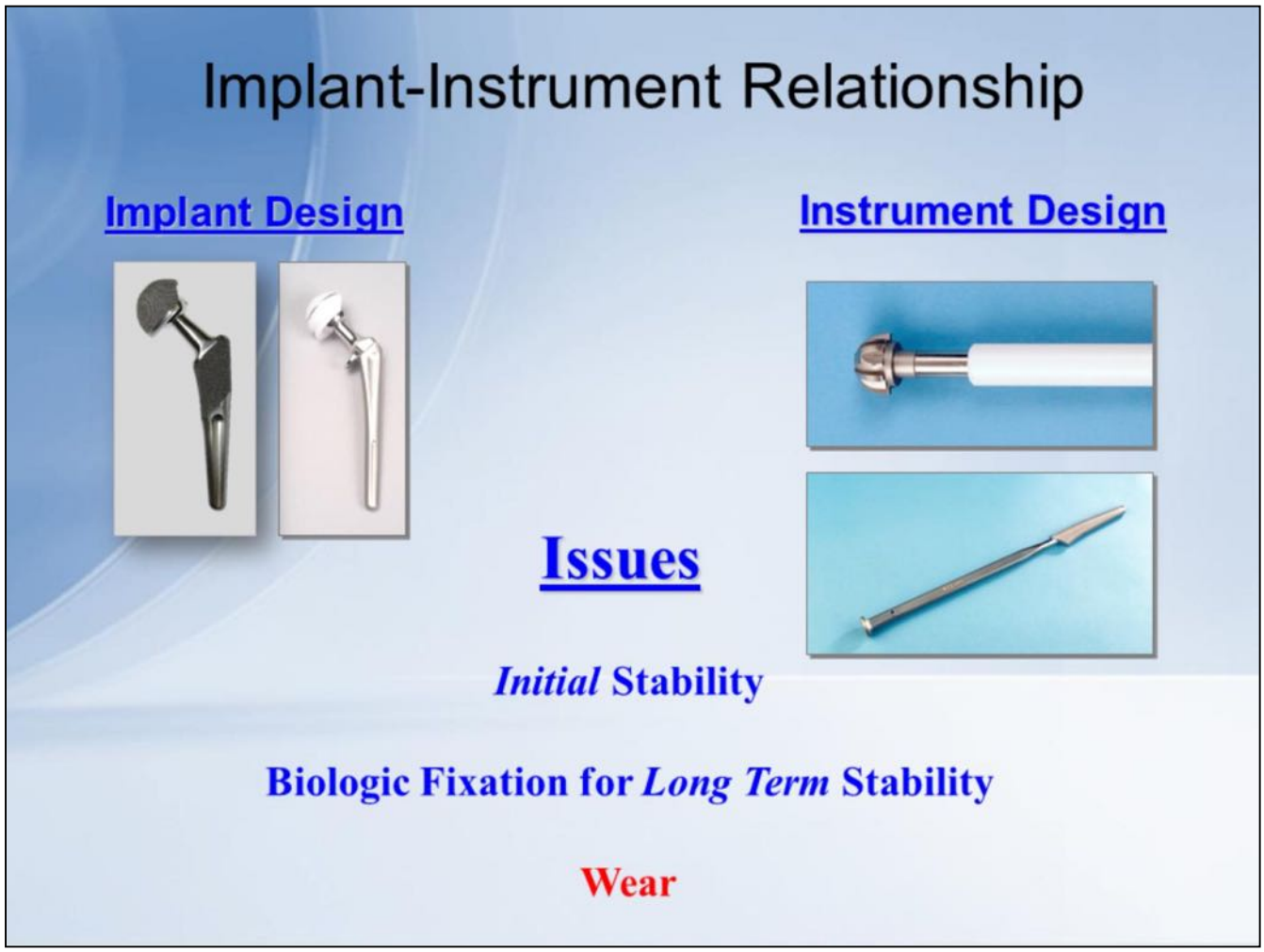
The EBM porous structure provides improved coefficient of friction over other clinically successful ingrowth surfaces.



The same surgical technique is followed for the BFX Collared Stem. However, there is a separate document, Helpful Hints for the BFX Collared Stem, which is recommended reading for the use of this product.



This is a clinical example of the collared stem providing resistance to post-operative stem subsidence.



In order to have cemented or cementless options within the same system

A common surgical technique is needed—and that technique must be driven by the more accurate of the two designs.

Therefore, the preparations are accurate and common so that a press fit can be achieved or

A cemented application can be achieved in that same prep by using the CFX system components.

So the objectives of the instrument design is to achieve initial stability for the cementless implants.

This is created through the interference fit; implants are approximately 1mm larger than the preparations.

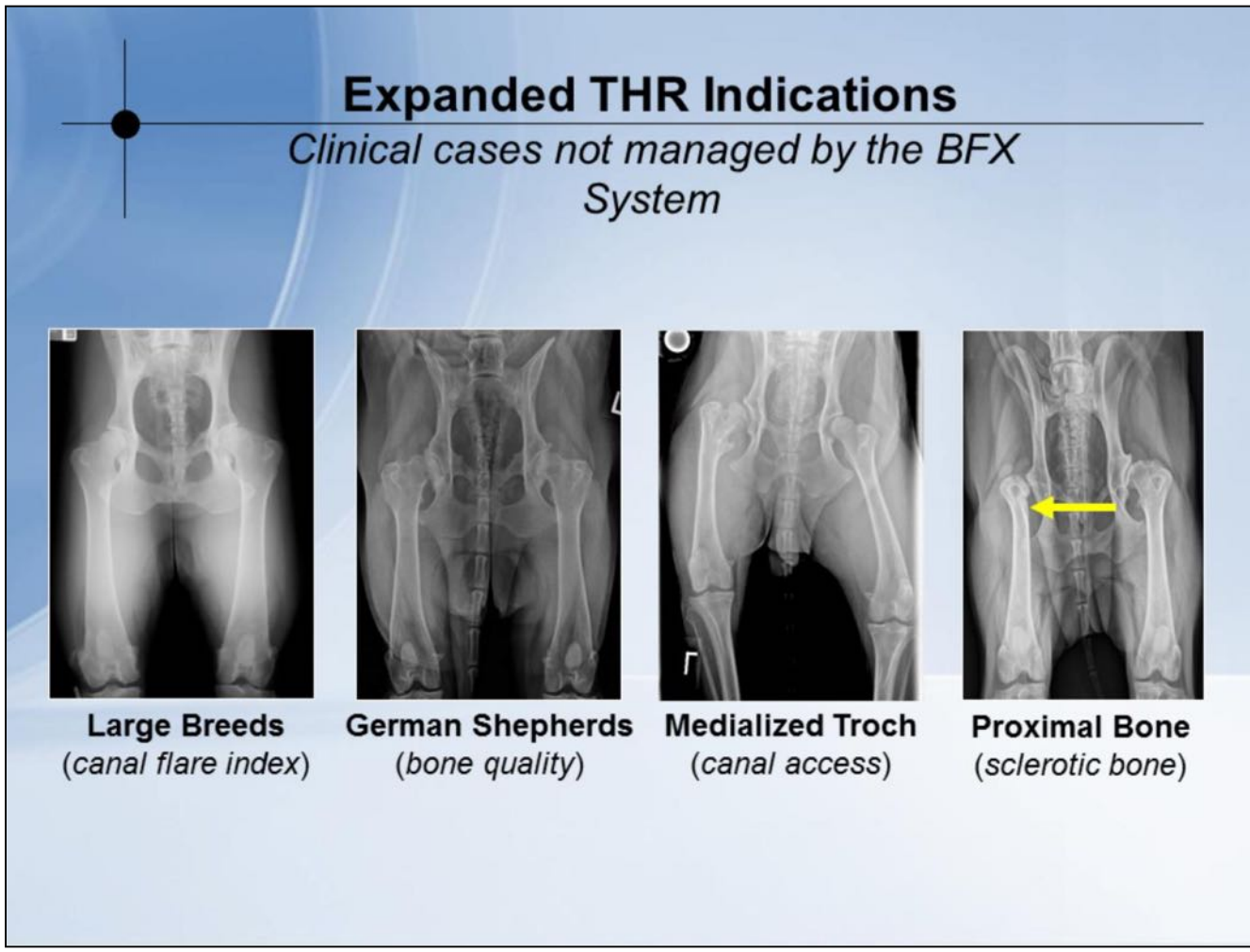
The stability from time zero to 8 – 12 weeks must keep the implants fixed; less than 75-100 microns. If relative motion between the implants and the bone exceeds that, you will not get bone ingrowth, but fibrous ingrowth.

Long term stability will be afforded only by bone ingrowth in the hip.

The finally, I will mention couple points about wear. If you achieve the other objectives, these can be undermined by wear.

Wear debris can cause osteolysis and lead to loosening and failure.

The Centerline stem is another addition to the Universal Hip System which further expands THR indications.



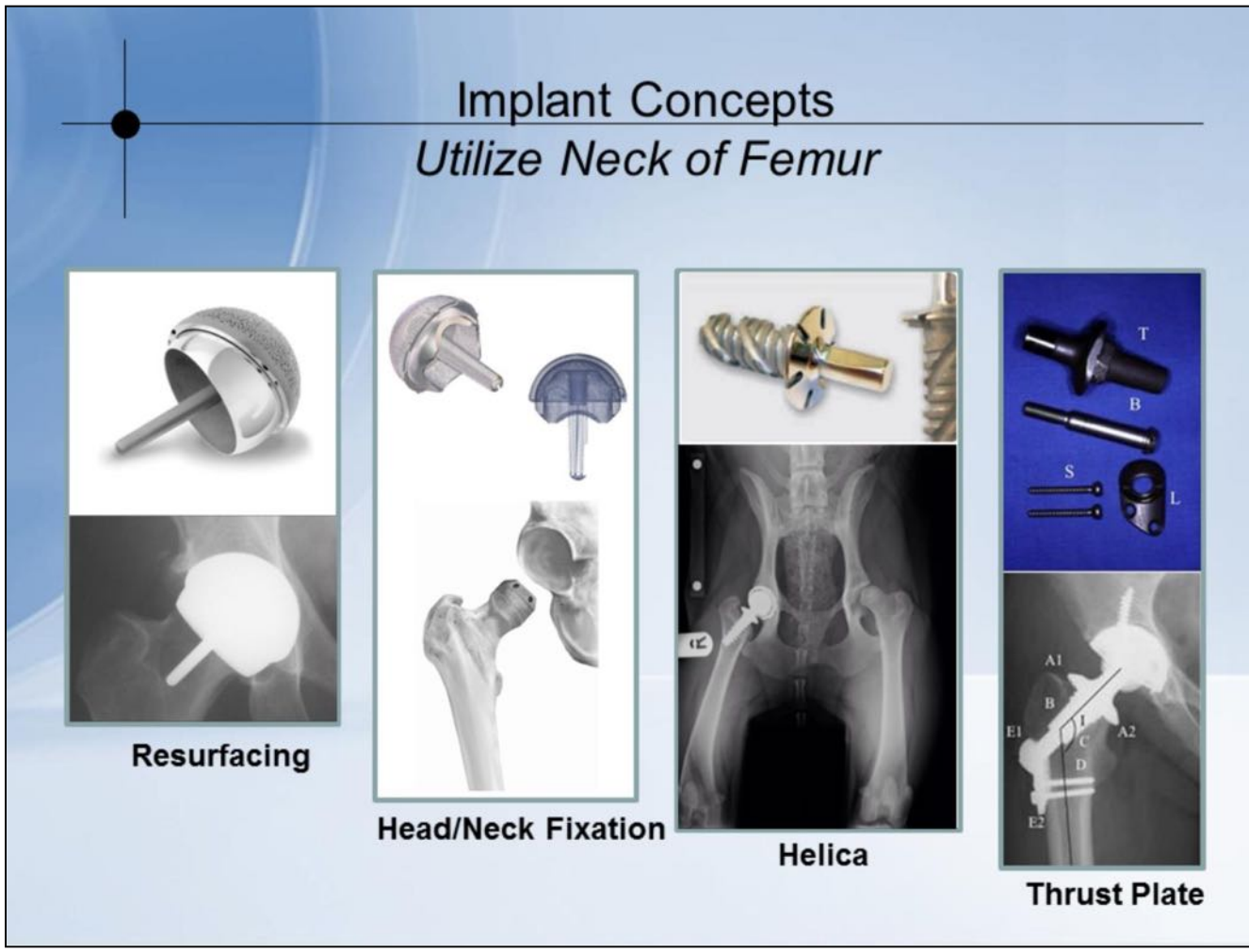
There are several clinical hip indications which can not be managed by the BFX cementless system.

Large breed dogs can have a canal flare index with a geometry more like a pipe leaving little resistance to subsidence.

German Shepherds have clinically demonstrated problems with subsidence due to cancellous bone strength and thin cortices leading to fractures intra-op and post-op.

Medialized trochanter can prevent access to the centerline of the femoral canal. It requires a trochanteric osteotomy or a preparation around the overhang with the use of a cemented stem.

In post-op FHO cases and in dysplastic hip cases, there can be a sclerosis of the cancellous and cortical bone leaving a very difficult access to the canal centerline. Even after reaming this area generally results in a smaller than desired press fit stem.



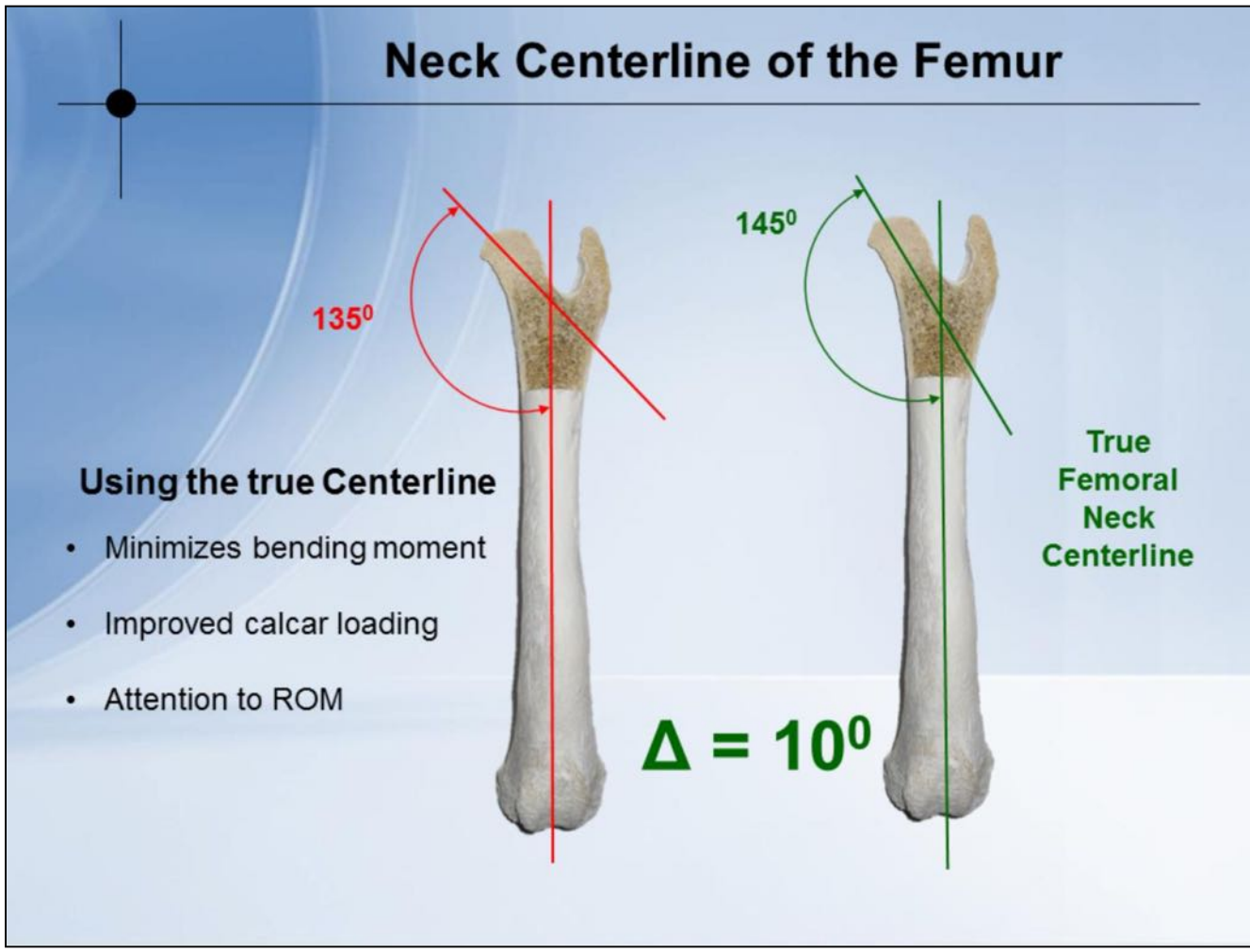
THR's have a long history with designing implants which are fixed within the neck of the femur. Here are a few. There are issues with

Resurfacing: historical very good but with metal-on-metal these have been recalled

Head/Neck fixation: generally these have demonstrated inadequate support by the remnant femoral neck/head bone leading to fracture or loosening thru osteonecrosis.

Helica is based on a human design. Both have shown issues with initial fixation and long term loosening. Relatively large implant within the cancellous bone of the neck and proximal femur.

Thrust Plate: originally developed in the late 1970's, has had good and bad results. There are a lot of parts which can lead to micromotion , wear debris and loosening.



To properly support an implant, it should follow the centerline of the canine femoral neck.

Hip stem implants have been at 1350 since the early 1970's with the Richard's Canine Hip and the PCA hip.

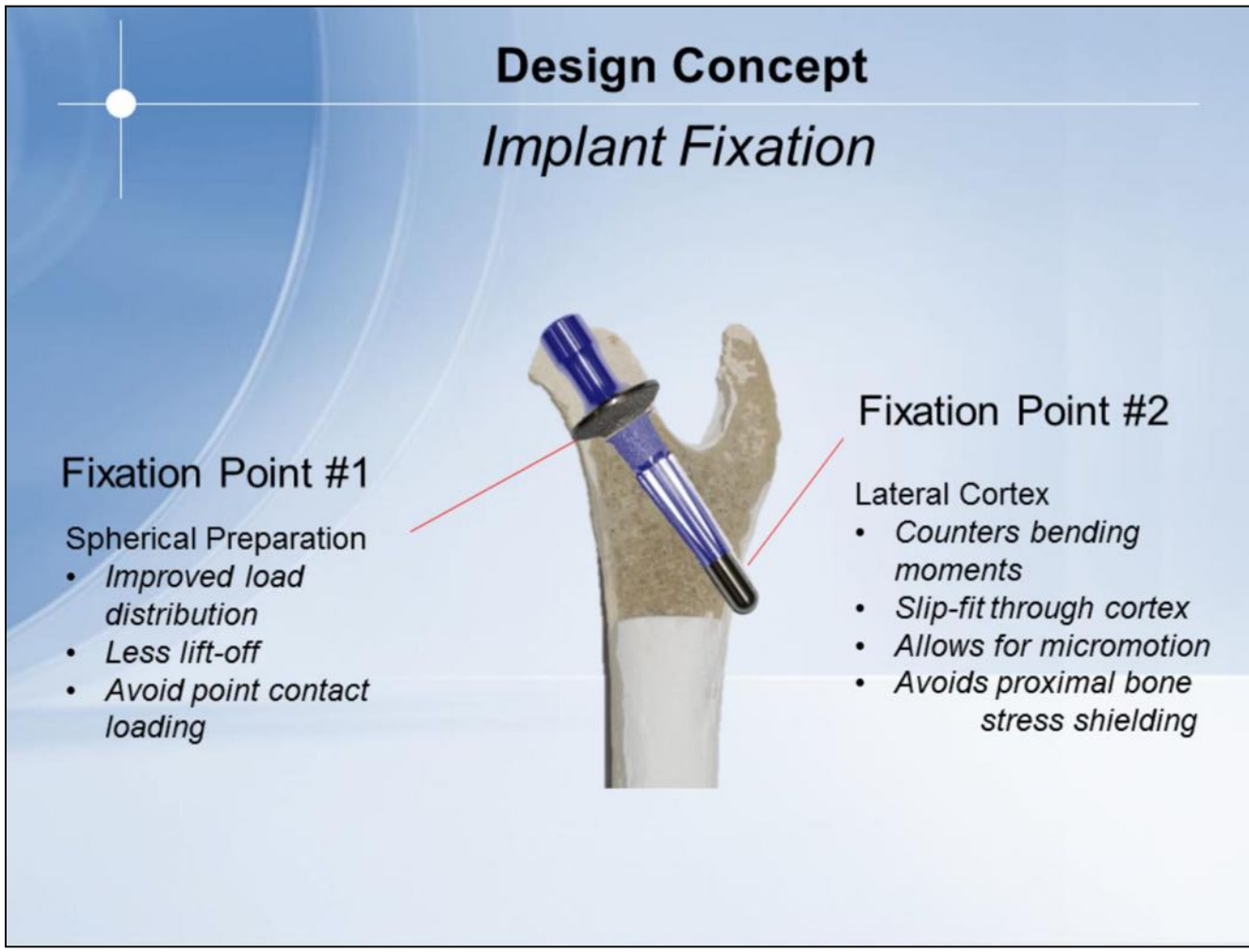
The true anatomical angle of the femoral neck is 1460 +80.

So an implant needs to follow this centerline. A straight implant can do this and be positioned based on each case.

Benefits are

- minimizing bending moments
- improved calcar loading

Attention needs to be given to the range of motion (ROM).



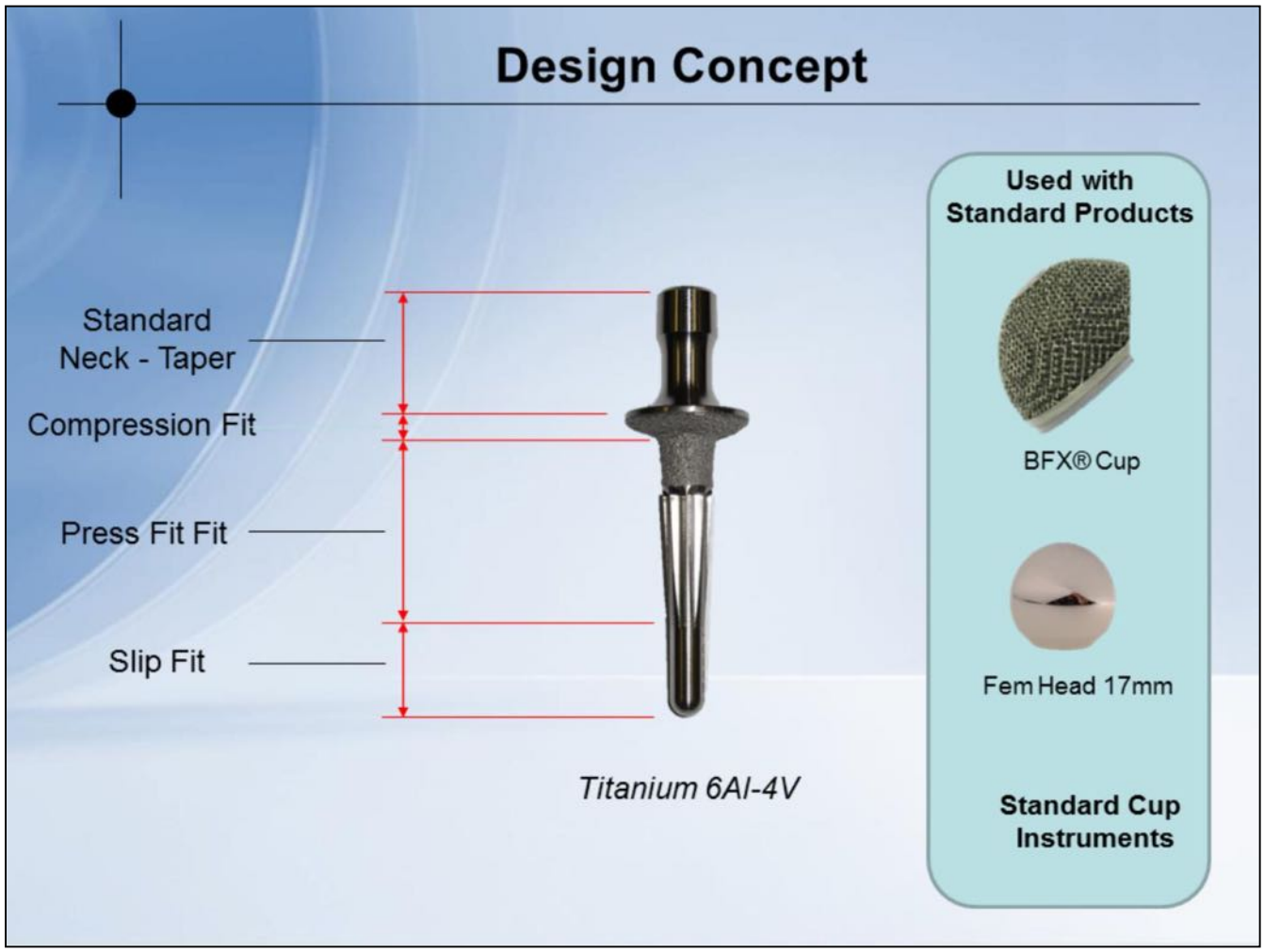
Long term success will be predicated on the initial fixation – even more so than the bone ingrowth surfaces.

Two (2) points have been incorporated into the design to achieve this:

1. spherical neck preparation similar to the BFX cup preparation
   - provides improved load distribution
   - less lift-off
   - avoids point contact of collar from offset loading
2. Lateral cortex: polished stem tip passes thru the lateral cortex
   - counters bending moments created during normal loading at the femoral head
   - slip-fit thru the cortex prevents ingrowth and therefore stress shielding of the proximal bone.

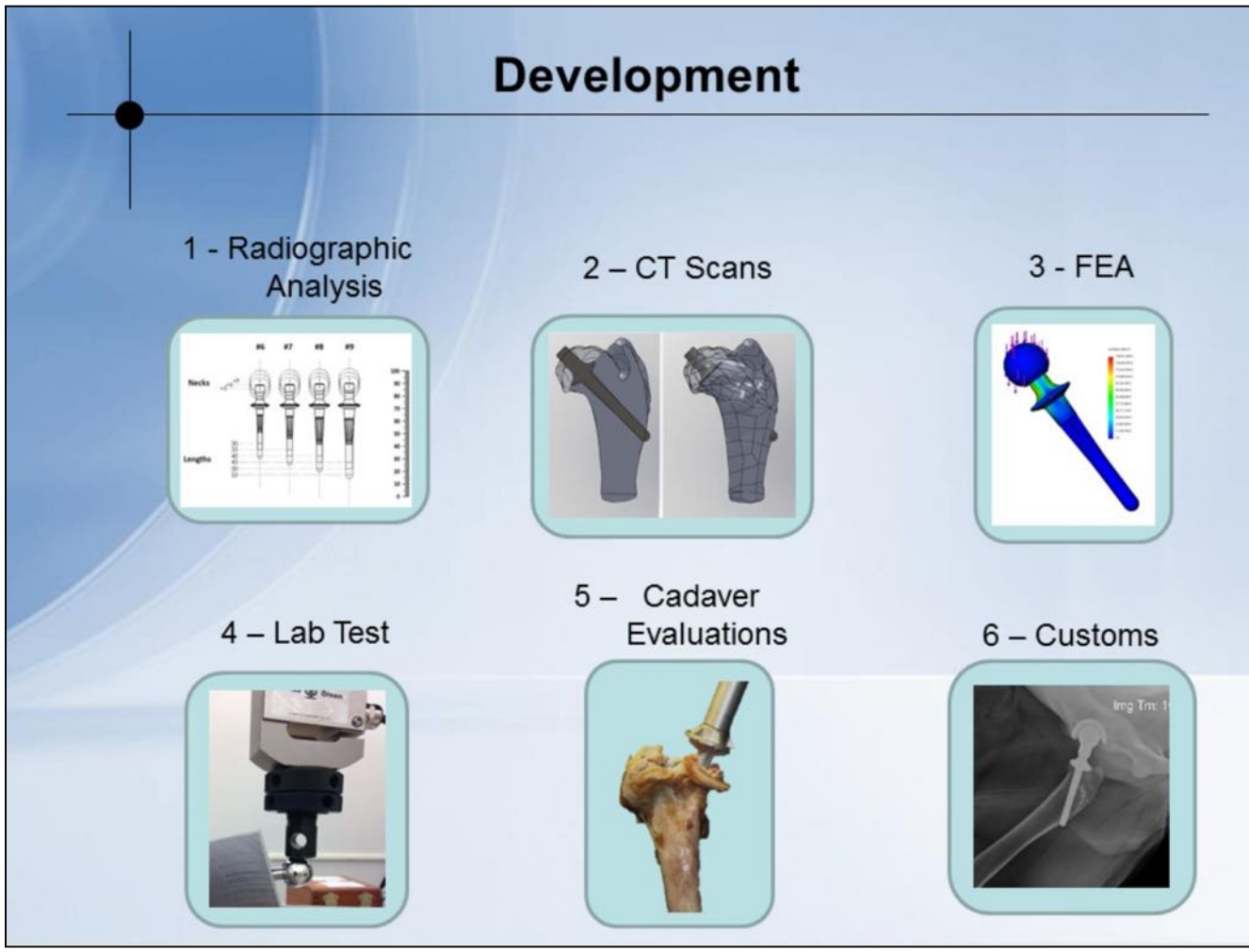
If the stem tip has bone attach to it, then the bone at the proximal (opposite end)

of the implant will see less stress and could resorb.



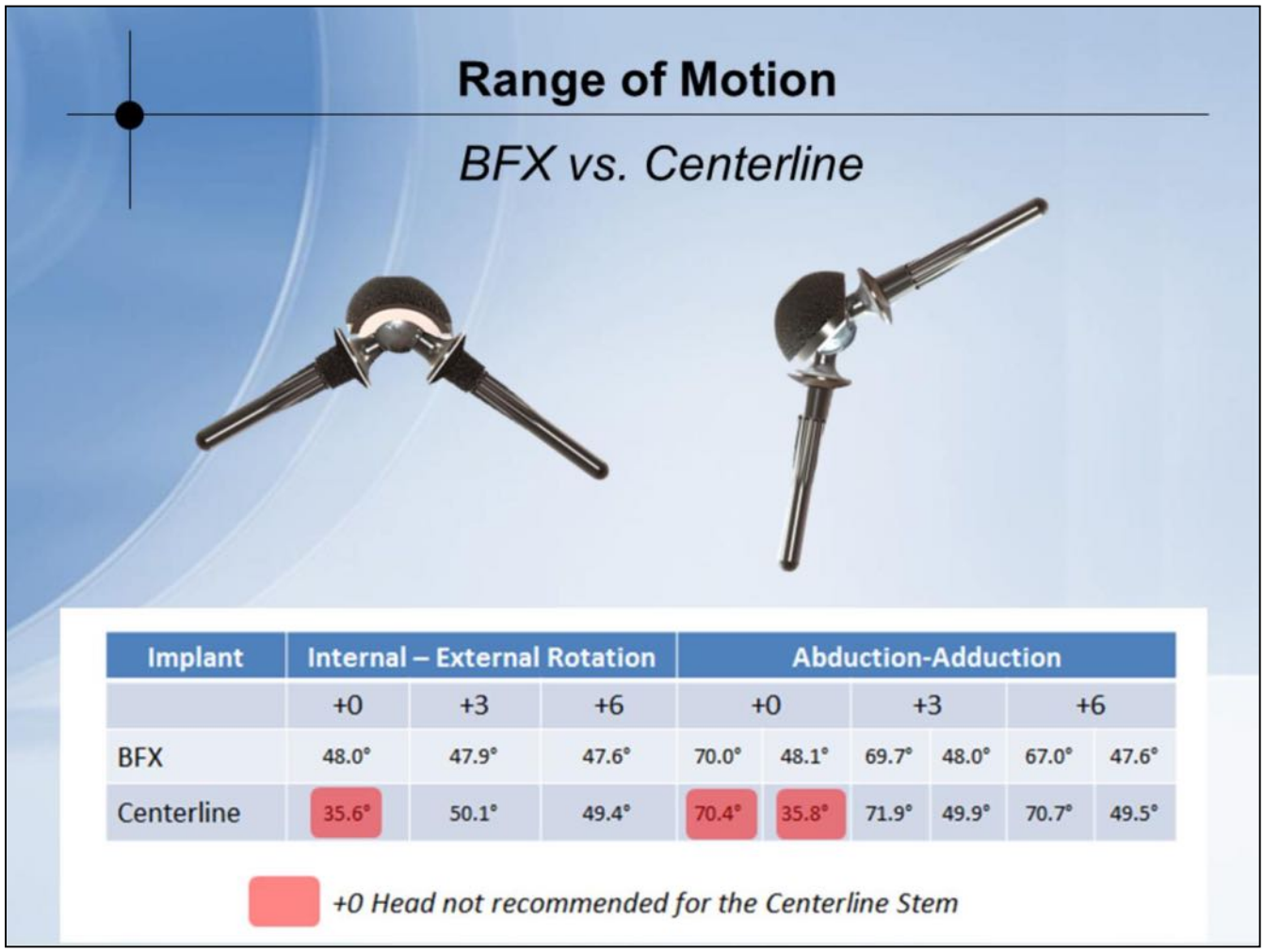
Implant is designed for the preparation to be machined and to achieve specific fits within that preparation:

1. Compression Fit at the collar: femoral neck is spherically prepared so the spherical collar rests within that prep for compressive loading the bone
2. Press Fit: he conical section of the implant below the collar is designed to be press fitted to a specific interference. It also provides torsional resistance thru the stem splines.
3. Slip – Fit: the distal portion of the implant has a slight clearance fit with the drilled hole in the cortex and it is polished to avoid bone attachment. This allows slight micromotion of the stem thru this hole as is needed through the proximal femoral loading.



With these design principles, we have continued research in the following areas over the last two years:

1. radiographic analysis in defining the stem geometry for sizing
2. CT scans to support neck canal fill
3. FEA (Finite Element Analysis) to assure static and fatigue carrying ability of the implant
4. Lab testing to support the computer analysis
5. cadaver evaluations to validate implant fit and define the surgical technique and necessary instruments
6. we initiated custom implant cases in August 2010 with Gary Brown following the basic development in each of these categories.



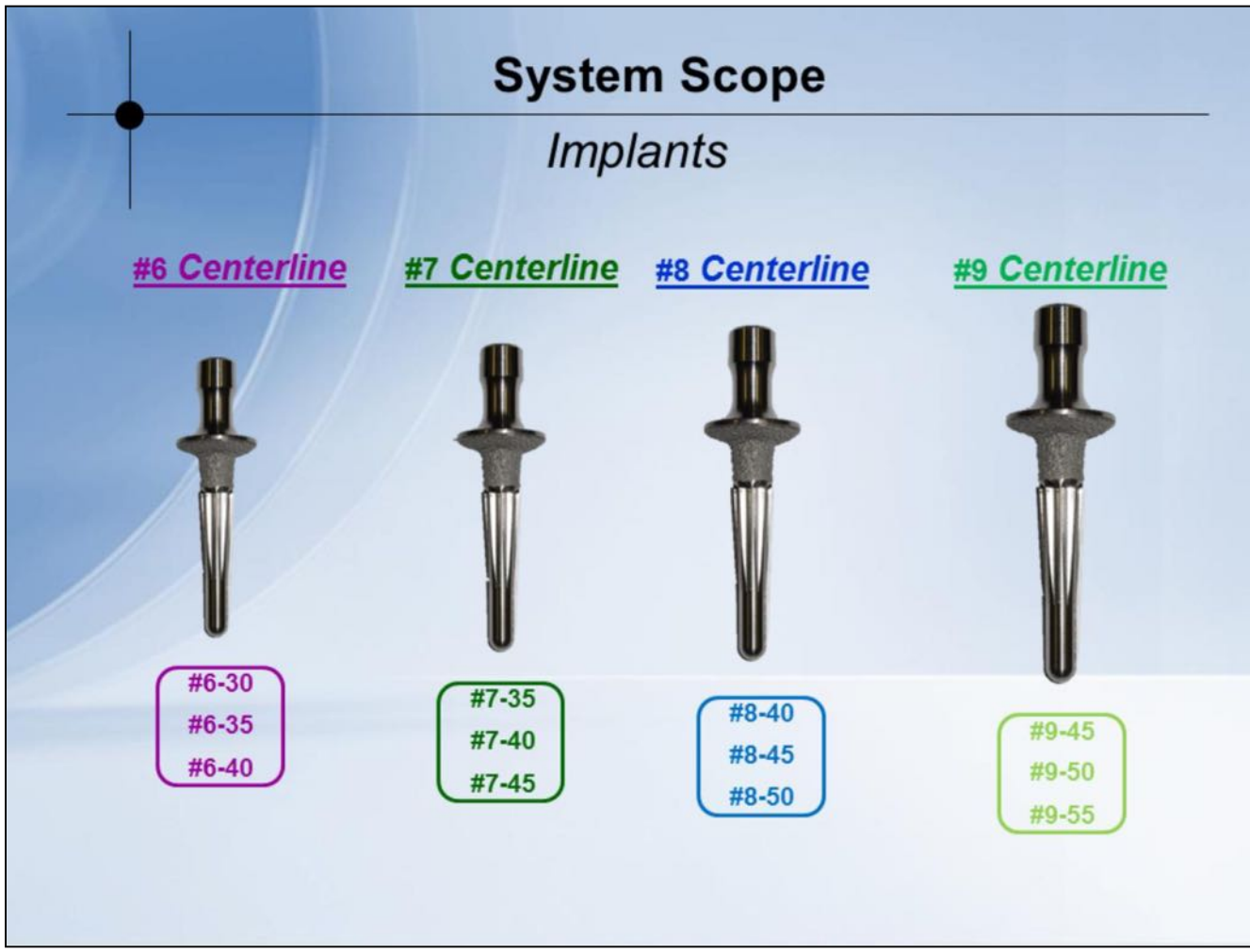
Range of motion analysis was performed for the Centerline Stem. The +0 neck length for the 17mm head is not recommended due to the reduced range of motion.

There are a few surgical technique differences between the Centerline stem and the BFX stem.

Cup position for the Centerline should be in a more closed position (up to 10 degrees) due to the increased femoral neck angle of the stem.

The Centerline also requires a higher neck resection; approximately 6mm less bone is removed.

The Centerline Stem has been designed in conjunction with the BFX stems so a revision from a Centerline to same size BFX stem is possible.

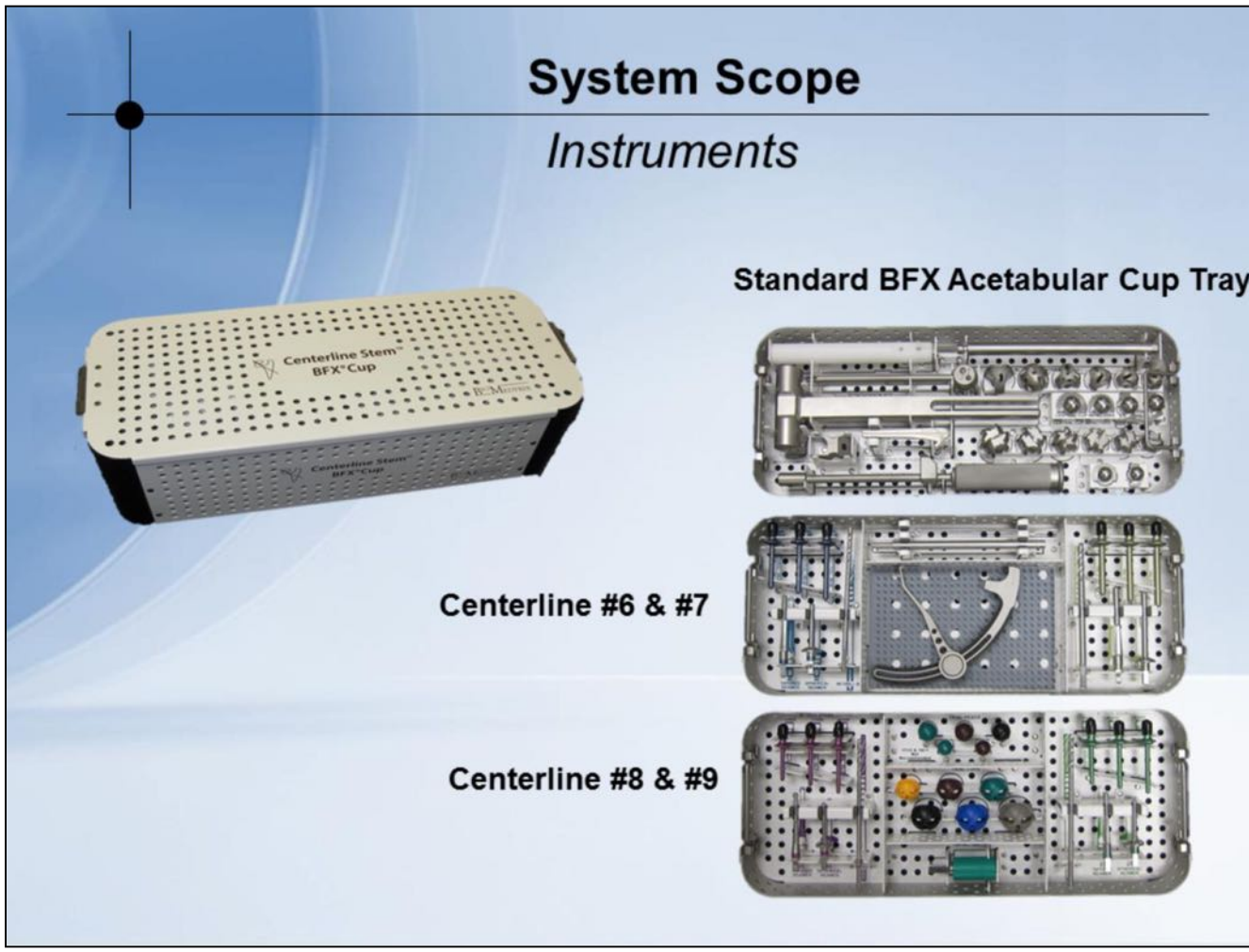


This is the scope of the femoral stem sizes. The clinical study we are looking to perform will confirm these sizes and lengths. Some may not be needed and additional lengths may be needed in some sizes.

The design concepts are expandable in either direction; sizes #4 and #5 along with #10 and #11. #10 and #11 are in process now and will be added by early January.

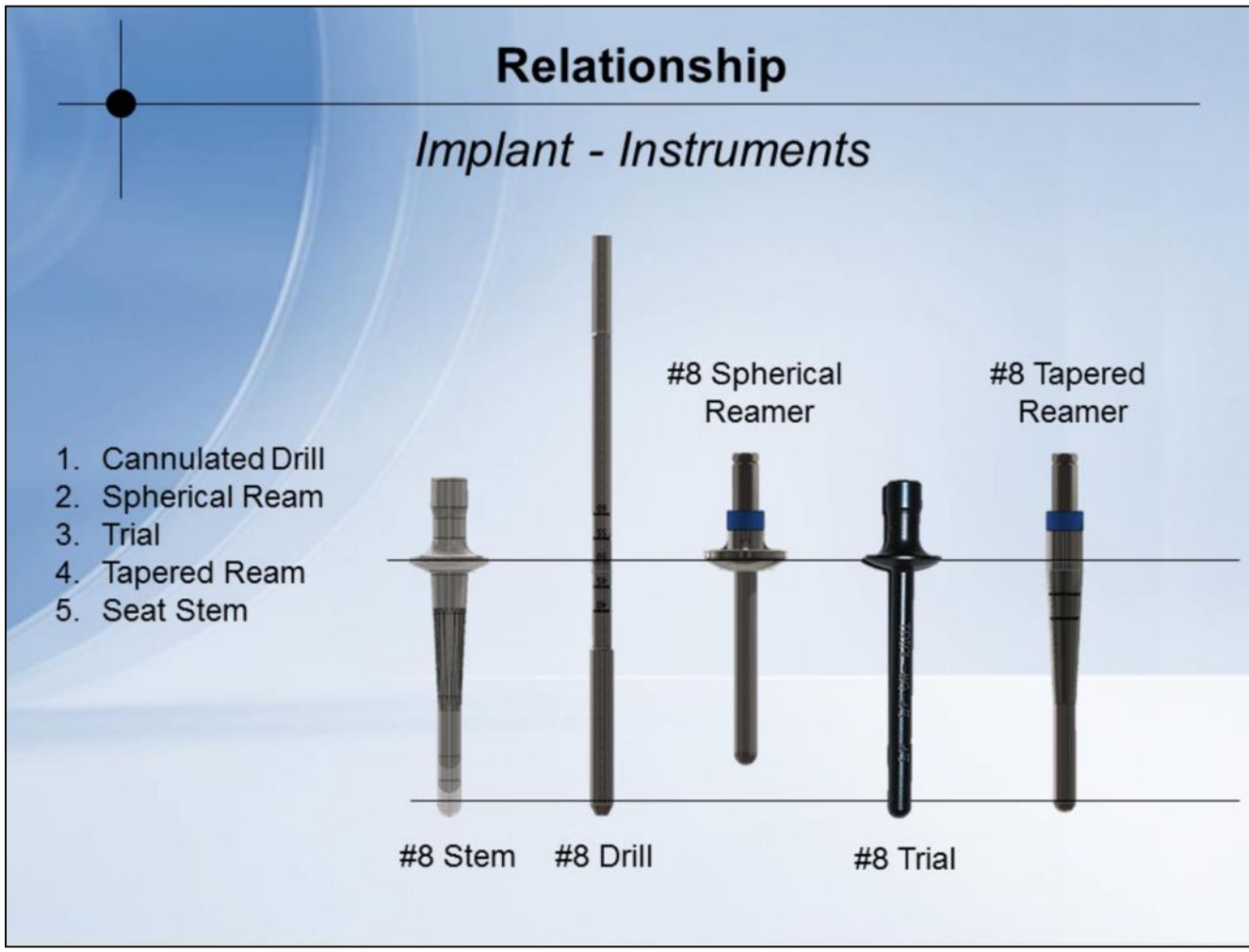
We will begin development of the smaller sizes once we have sufficient clinical feedback.

As you can see, each size overlaps the stem lengths of the next size.



The instrument case has three (3) trays:

1. The standard BFX acetabular tray can be placed within this case.
2. The second tray is composed of the #6 and #7 Centerline stems instruments
   - instruments in the center of the tray are common and can be used for any size
   - common instruments: 2.3mm guide pin, reamer shaft, drill guide
3. The third tray is composed of the #8 & #9 stems
   - instruments in the center of the tray are common and can be used for any size
   - trials heads (except no +0 17mm head), trial cups, Stem-Head impactor

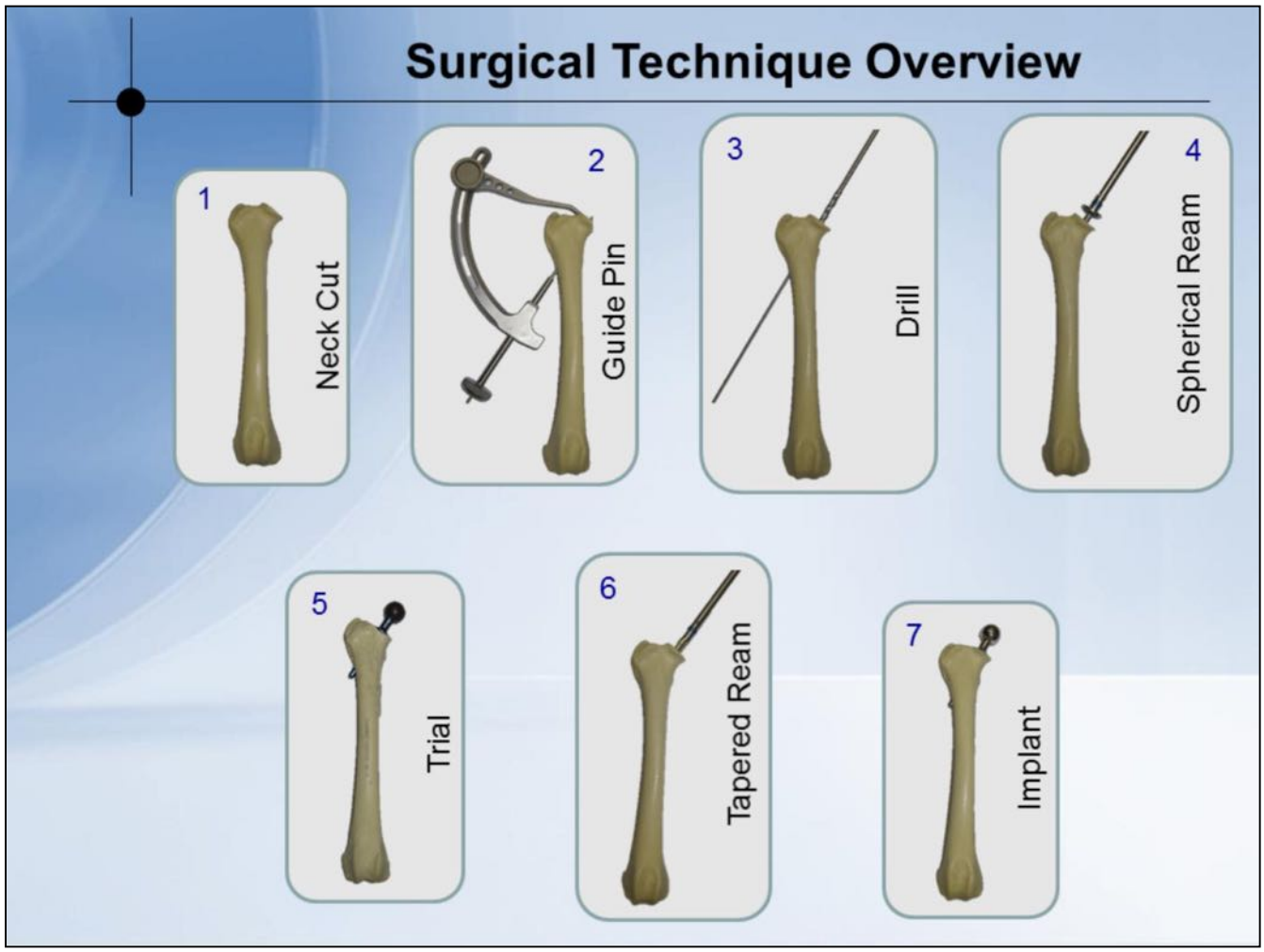


This is the relationship between the implant and the instruments.

The cannulated drill follows the guide pin (2.3mm) which was inserted using the Drill Guide. Drill is inserted until confirmed penetration thru the lateral cortex.

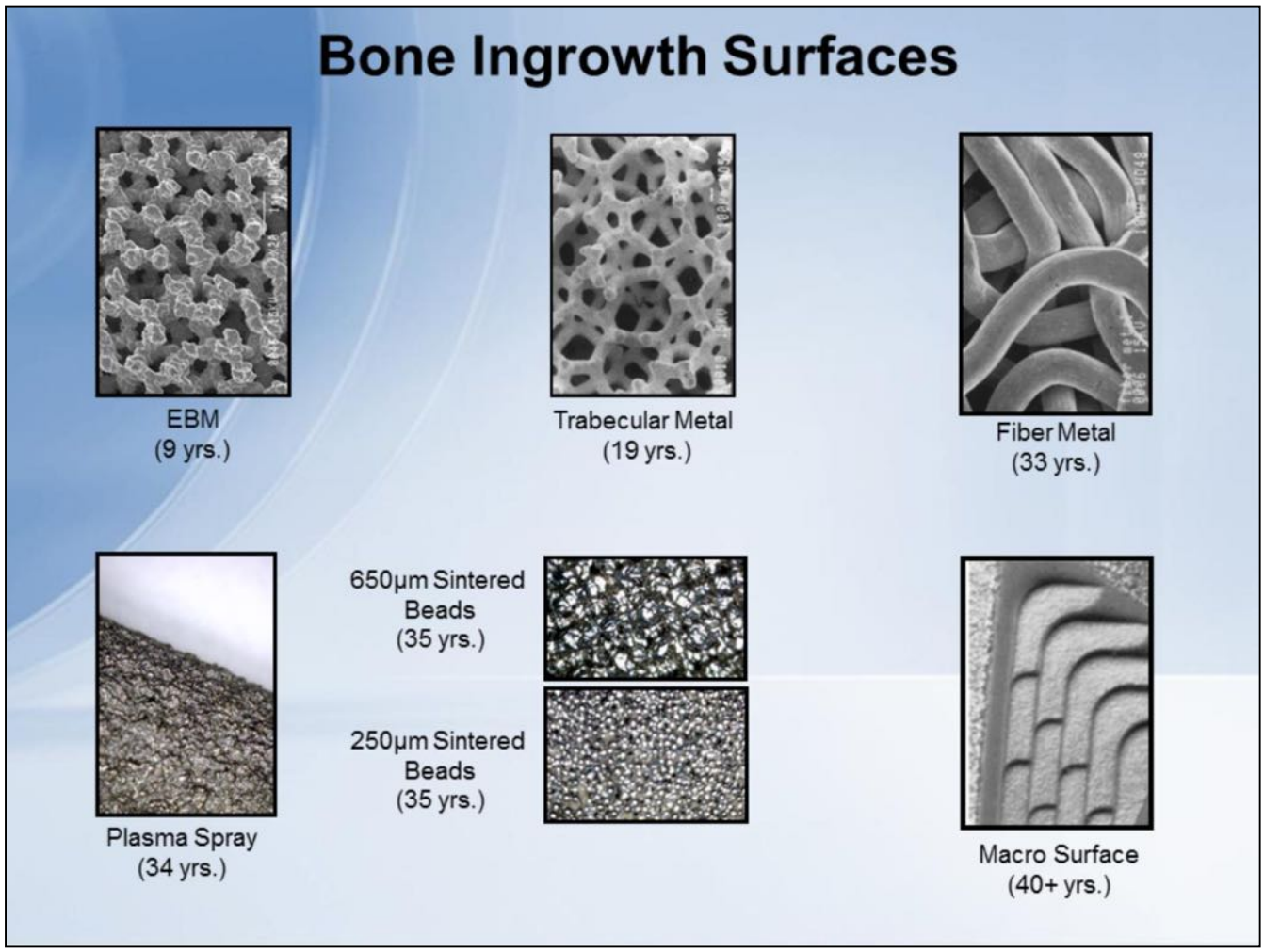
The smooth pilot on the spherical reamer is inserted and the spherical reamer introduced until the collar is flush with the head resection.

The trials are then inserted and a reduction is performed to establish the proper neck length.



The Centerline instruments and surgical technique are designed in light of that relationship. Different to the BFX system , the Centerline preparation is machined and only the insertion of the implant imposes a press fit hoop stress to the bone.

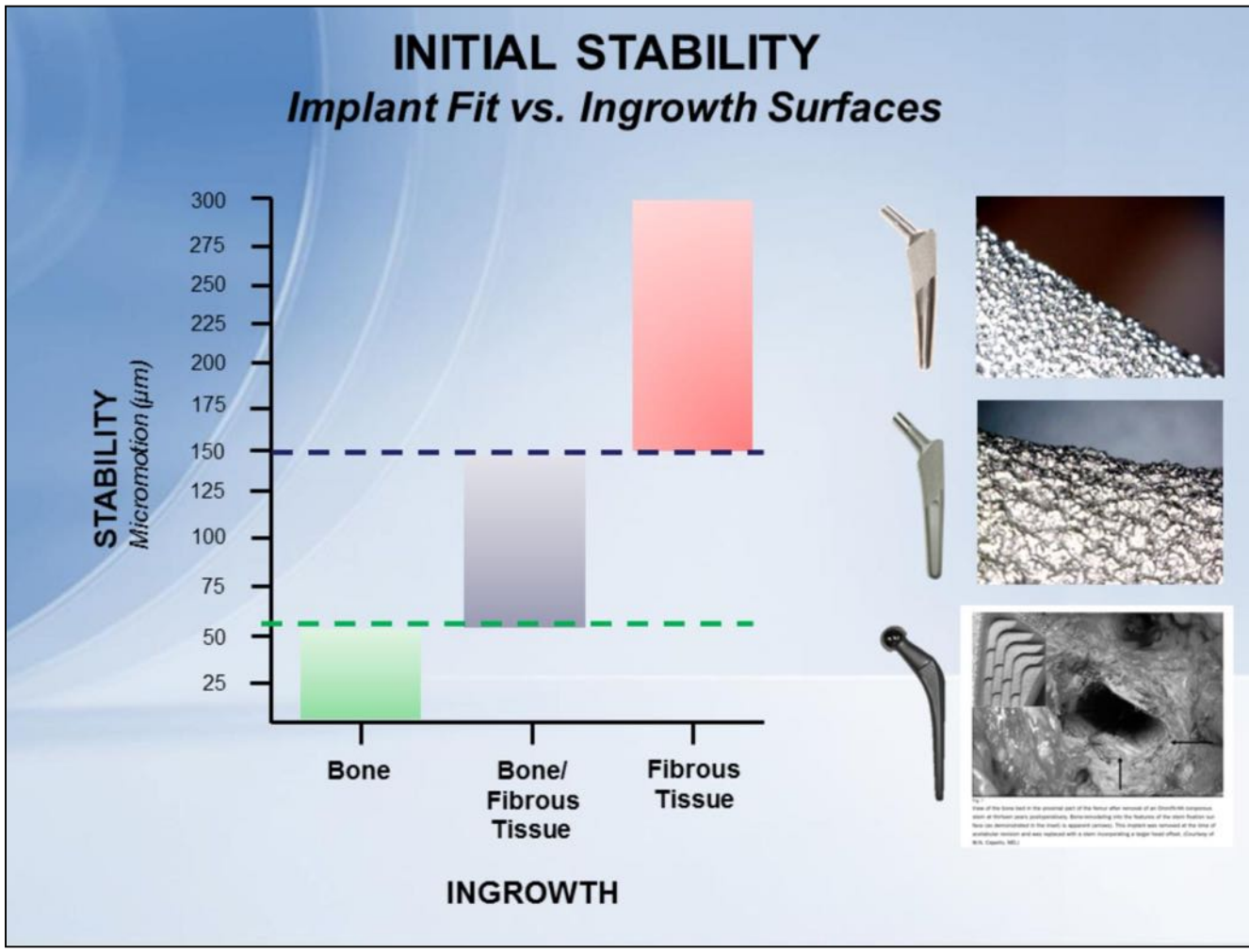
As with the BFX cup which is also a machined preparation, the Centerline stem press fit is a more predictable fit. It can also be adjusted based on the quality of the patients bone; increase if weaker bone or decrease if stronger bone.



Initial stability is key to long term success. This is achieved first through accurate instrumentation and next through bone-implant surfaces.

All these surfaces have been clinically successful in stabilizing implants to bone. The macro surface is still used today by some companies. If the preparation is correct, it can also be successful without an ingrowth capability.

However, any of these surfaces in a poor preparation will lead to aseptic loosening.



Initial stability is the key to long term success.

Above 150 microns of initial implant movement has been shown to generate a fibrous tissue response at the implant interface and not bone. In the hip, this can lead to aseptic loosening and removal of the implant.

On the right top, this is sintered bead technology (beads are fused to the surface of the implant) which was developed in the late 1970's.

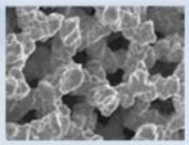
The photo below that is a plasma sprayed titanium surface. This was developed in the early 1980's.

The last photo is an implant retrieved (Omnifit Stem, Stryker) after 13 years with a successful outcome. This stem design had a macro surface for bone stability as it preceeded the porous ingrowth technology.

However, as evidenced by the internal canal geometry of the femur, the stem was stable to a degree that allowed bone to growth up to the stem and create a negative of the stem macro geometry.

BFX® Stem - *Design Features*

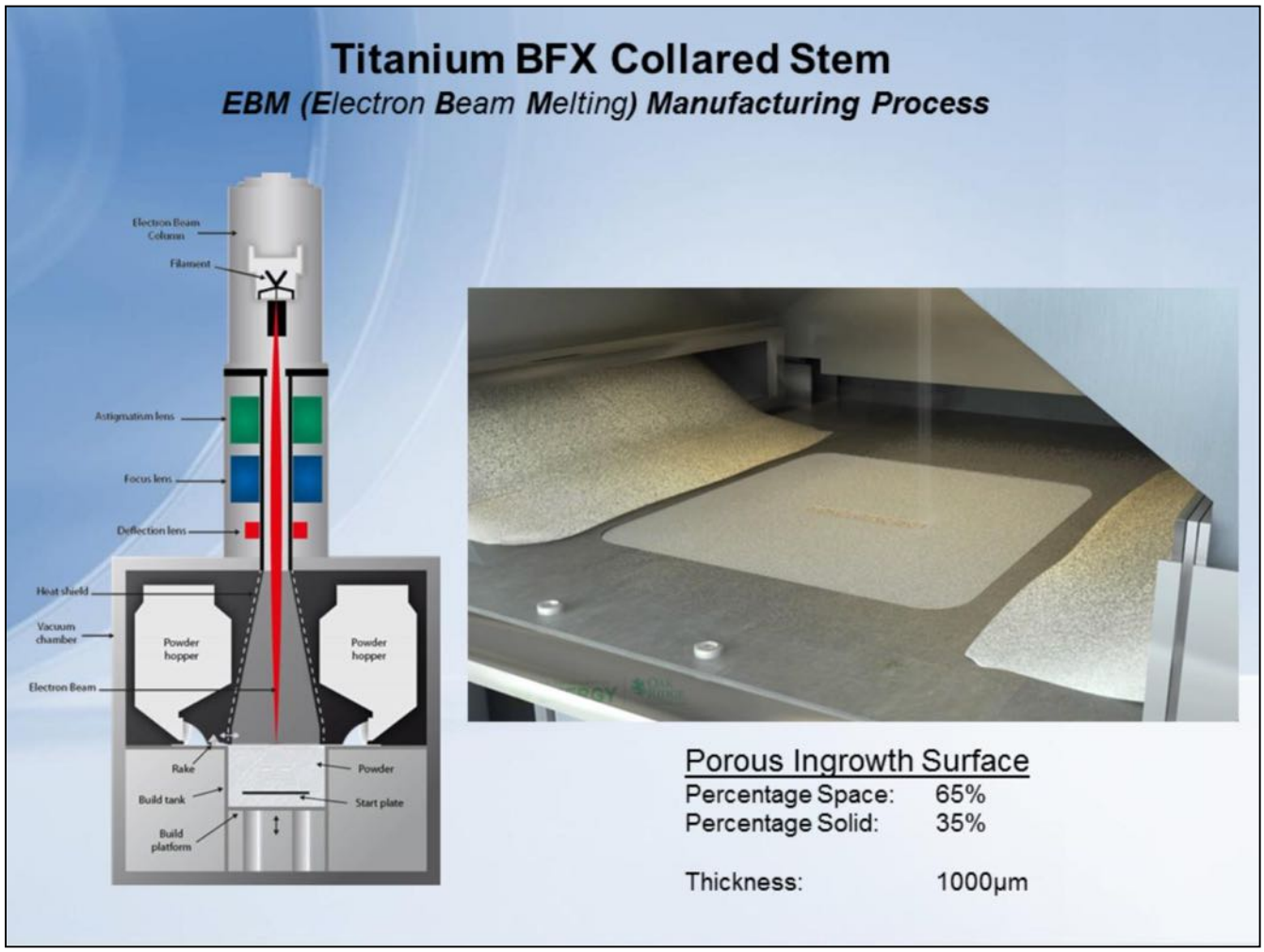
1. Stem Length
2. Neck Length
3. Proximal Canal Fit
4. Distal Canal Fit
5. Area Porous Coating: Circumferential & 45% proximal
6. Material: Titanium 6Al-4V (ASTM F-136)
7. Size Range: 9 Sizes
8. Neck Version: Neutral vs. 16^0
9. Stem Geometry: Straight, symmetrical for left and right



EBM Technology

*US Patent No. 7,547,328 & 7,169,185

Stem design encompasses several features which are key to long term clinical success.
In the development we reviewed both canine and human hip systems
incorporated design principles with over 25 years clinical success.



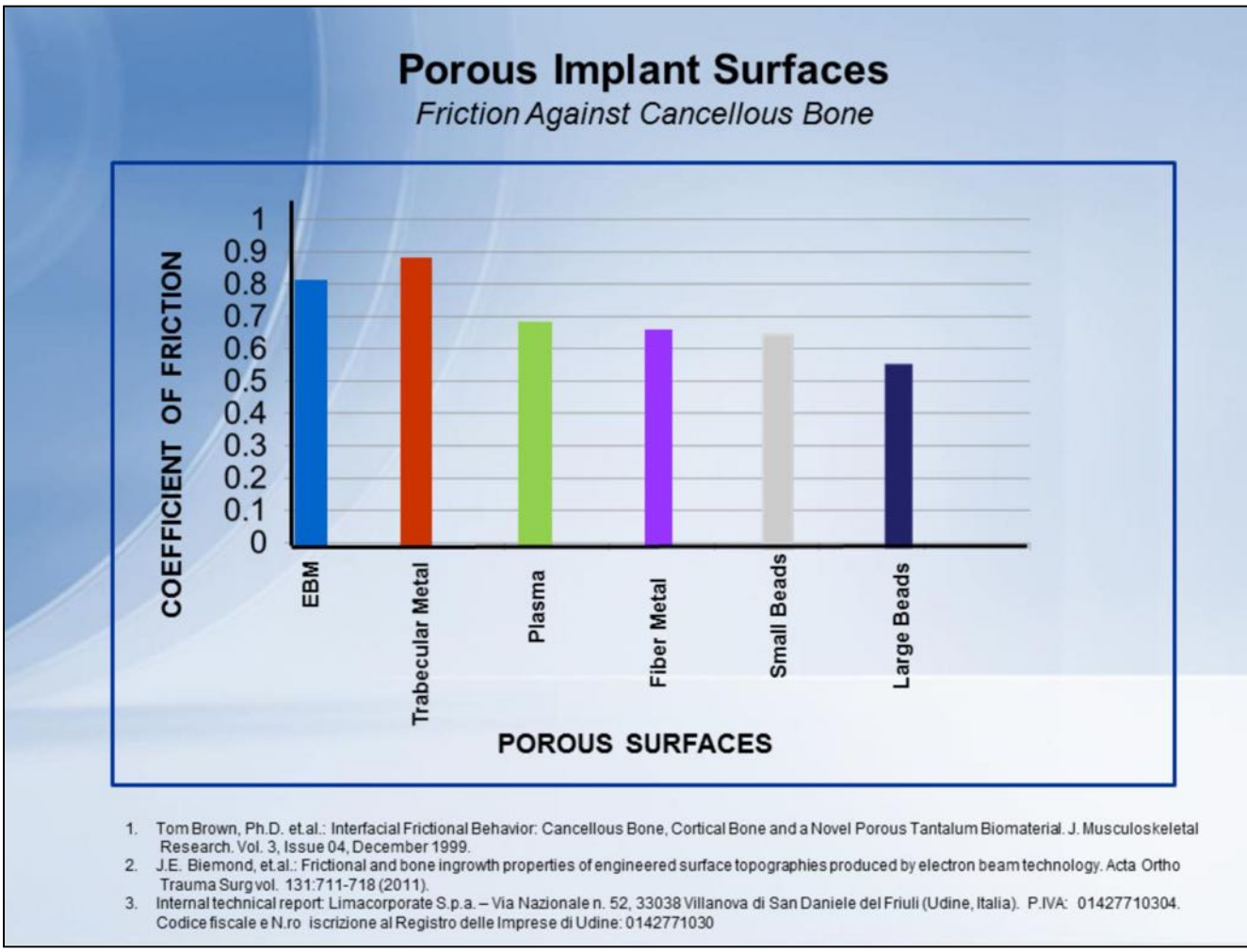
We are currently utilizing EBM for the manufacture of the BFX stem and cup.

It produces ASTM quality stems at the highest end of the mechanical property spectrum.

This process is used in automotive, medical, aeronautics and aerospace.

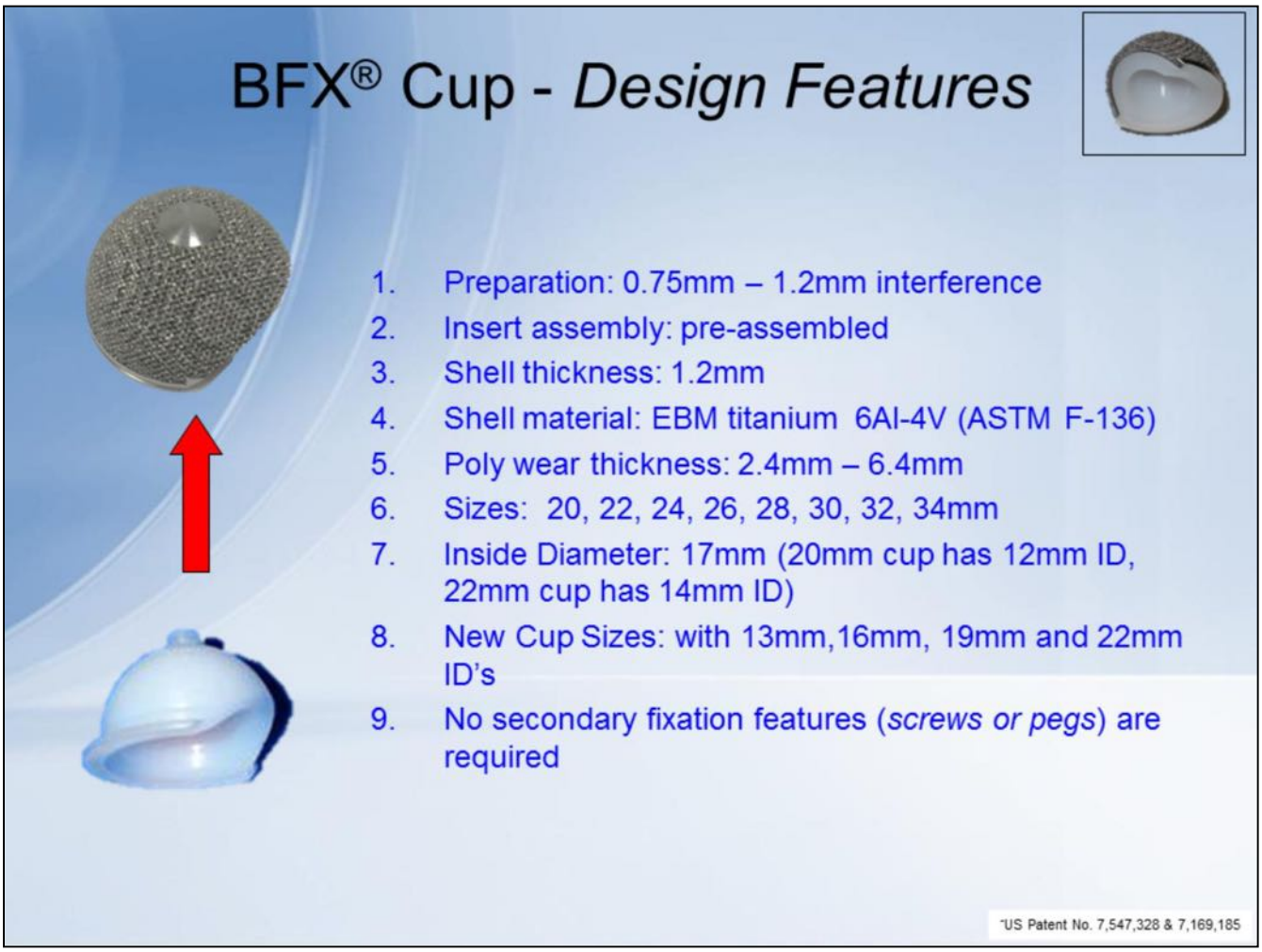
Generally it starts with a bed of pure titanium powder (specific particle size) and using as computer model of the part, scans the bed of powder in 50 micron layers—similar to how a CT scan works in creating a 3-D model of a particular aspect of the body.

Through repeated scans a part emerges from the bed of powder.



The porous titanium structure for ingrowth is an integral part of the component.

It is designed to create a very high coefficient of friction to improve the initial stability of the implant. Longer term fixation occurs through the ingrowth of bone into the pores.

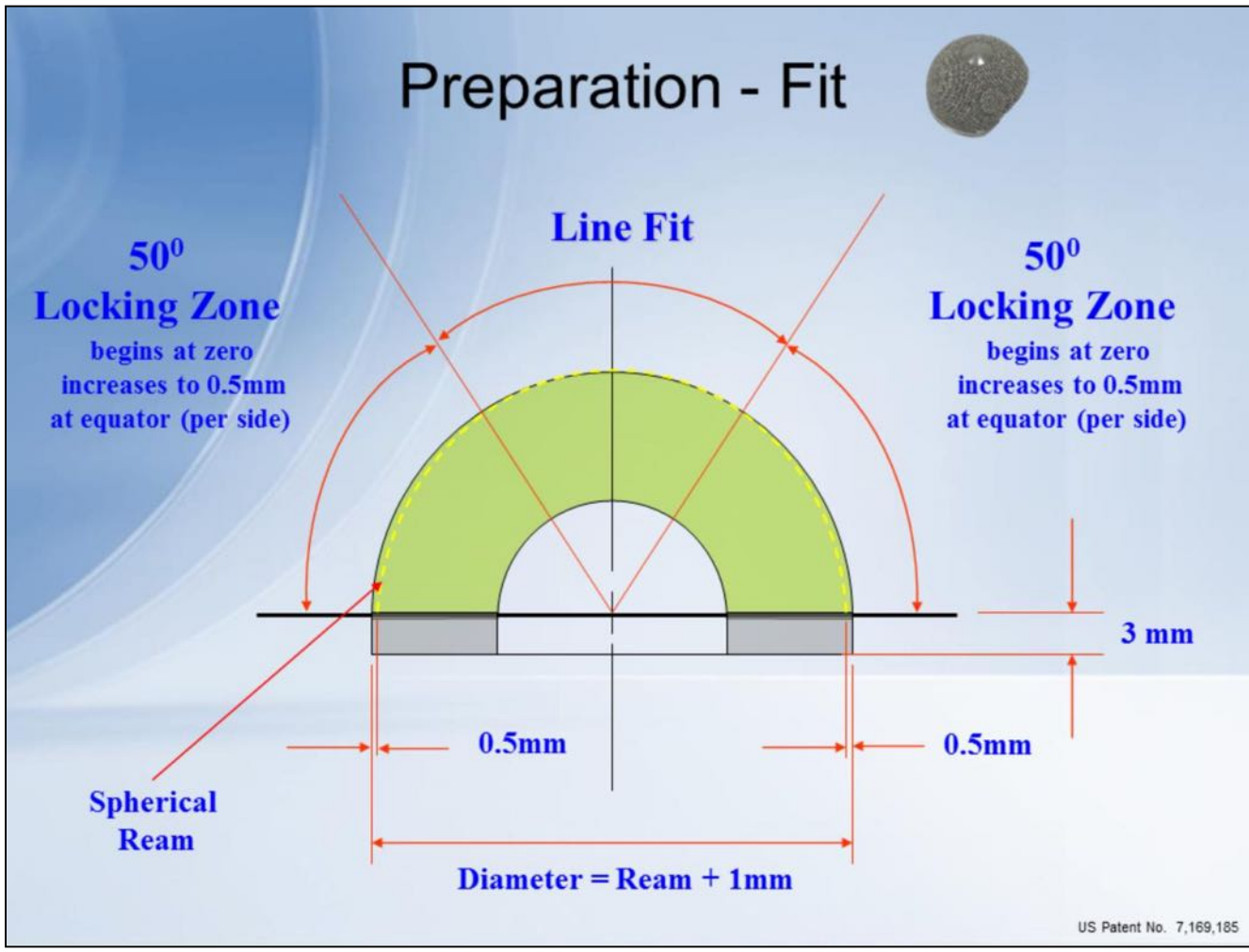


Regarding the cup design, the same design philosophy was followed referencing successful cup designs and applying improved design features for immediate stability.

An important design aspect of the cup is that it relies on an initial press fit which the outer geometry only.

It is mfg'ed thru EBM also.

It does not rely on secondary fixation features such as pegs or screws.



Cup achieves primary fixation without screws

Design is broken into different zones to achieve this initial fixation.

The dome area is a line fit to clearance relative to the prep. This area will actually prevent a press fit if there is interference.

Locking zones provide tangential fixation beginning at about 50 degrees.

From that point, interference starts at 0mm and increases to 0.5mm/side at the equator.

Cup then continues at 1mm interference in the cylindrical area.

This design affords you the ability to lightly press fit in the Locking Zone, make any necessary adjustments and then drive it home.

Once the cylindrical portion has engaged, the position can not be adjusted.

However, the cup can be removed from the preparation by impacting the dorsal rim of the cup and rotating it our of the preparation.

The prep is not damaged and the process and start again—we'll try this in the lab.

The other longer term concern I mentioned was wear.

Debris can negate all the benefits up to this point.

So the quality of the UHMWPE must be considered and proven.

There are three (3) primary mfg'ers (Orthoplastics, MediTECH and Westlake Plastics) of medical grade UHMWPE. They all start with the same powder, 100-150micron poly (Ticona GmbH in Germany).

How these mfg'ers process that powder actually determines the quality of the poly and its ability to resist wear.

They have different recipes of time, temp and pressure.

We began using Perplas in 1990 (now they are Orthoplastics) in England as they demonstrated the highest quality plastic.

As part of the QA/QC, they take a thin 50 micron section from the production material and analyze the consolidation of the plastic. It should look like the right.

If it looks like the left, these particles were not fully consolidated and become the starting point for generating poly wear debris—

And eventually osteolysis and loosening.

Orthoplastics provides this QC procedure for all plastic they ship for medical implants.

Head - *Design Features*

- Common head with CFX® and BFX® systems
- Head diameter: 17mm
- Neck length: +0mm, +3mm, +6mm, or +9mm
- Material: wrought cobalt chrome ASTM F-799 for improved surface finish
- Increased stability with a 17mm head
- Increased contact area for reduction in poly. stress

CFX/BFX Head

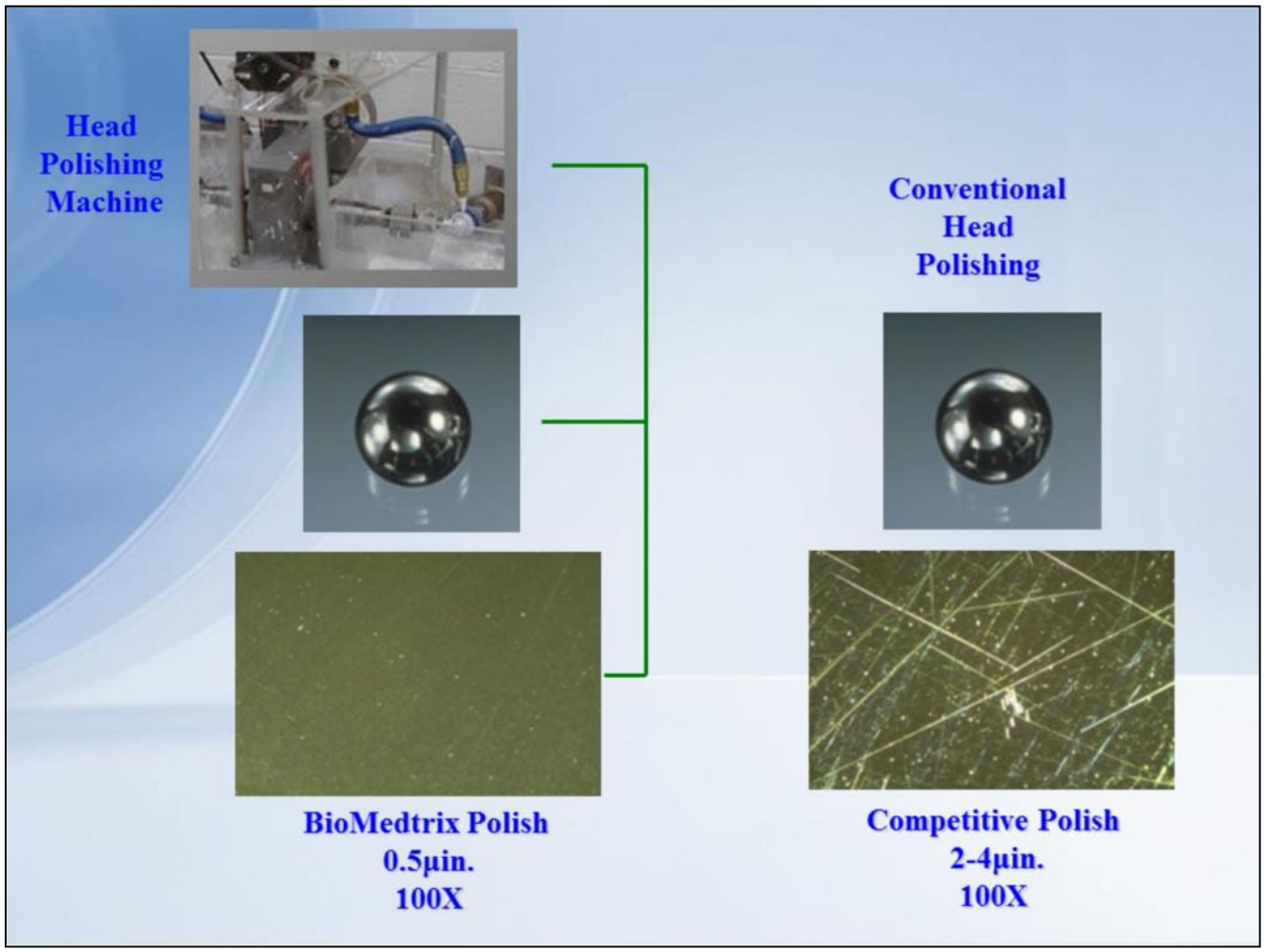
Once the quality of the poly has been established..

The head must be considered as it is the counterpart which can also generate wear debris

BFX/CFX heads are wrought cobalt chrome (as opposed to cast)

Harder material is better wear surface and it also can achieve a better polish

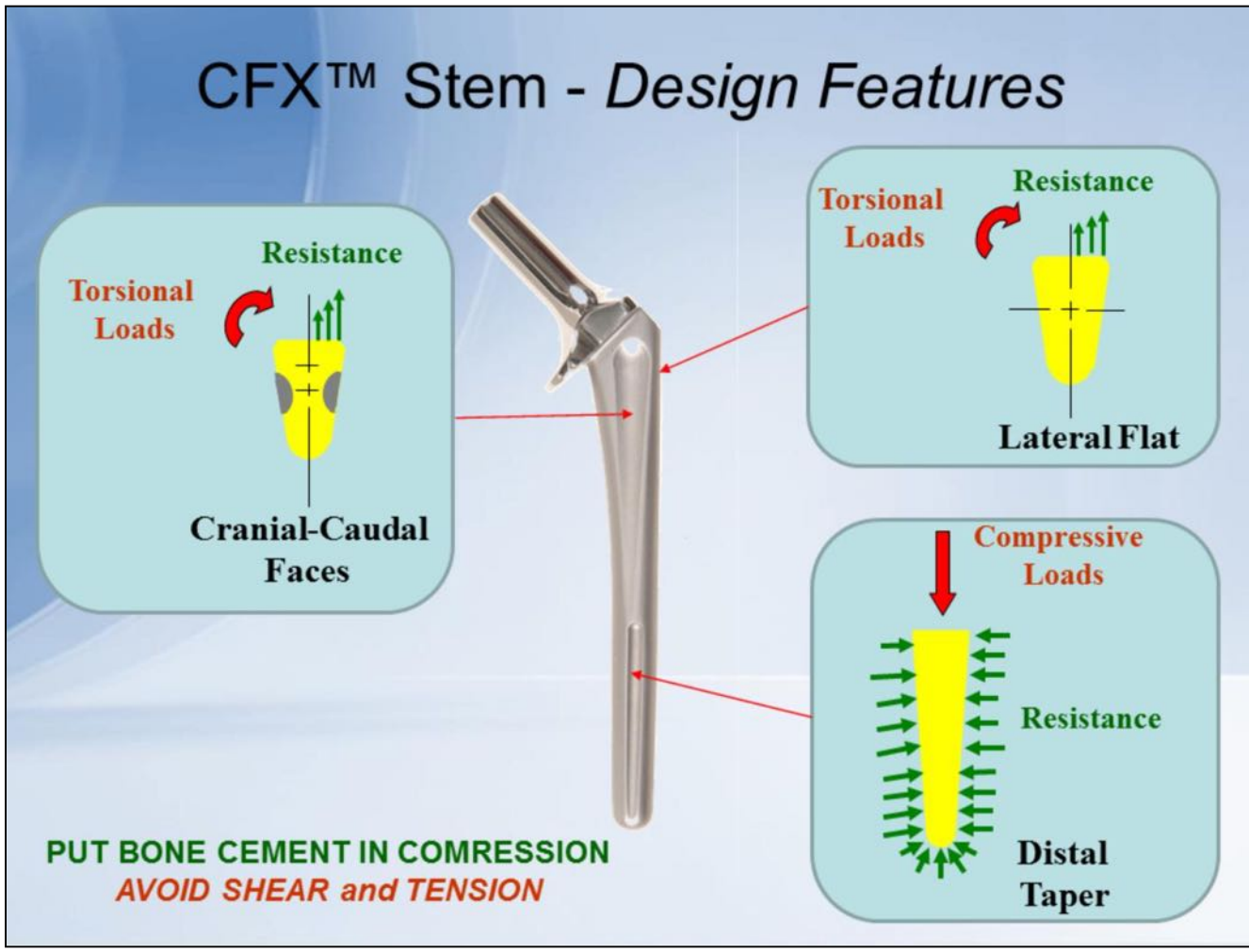
We have designed and built our own polishing machines to achieve surface finishes below 1 microinch. This is generally better than that in the human industry for most companies.



By eye, it is very difficult to see the difference in polish.

At 100x, you can see the potential problems with a rougher head finish.

Our QC involves 100X inspection to assure optimum head finish in order to address wear.



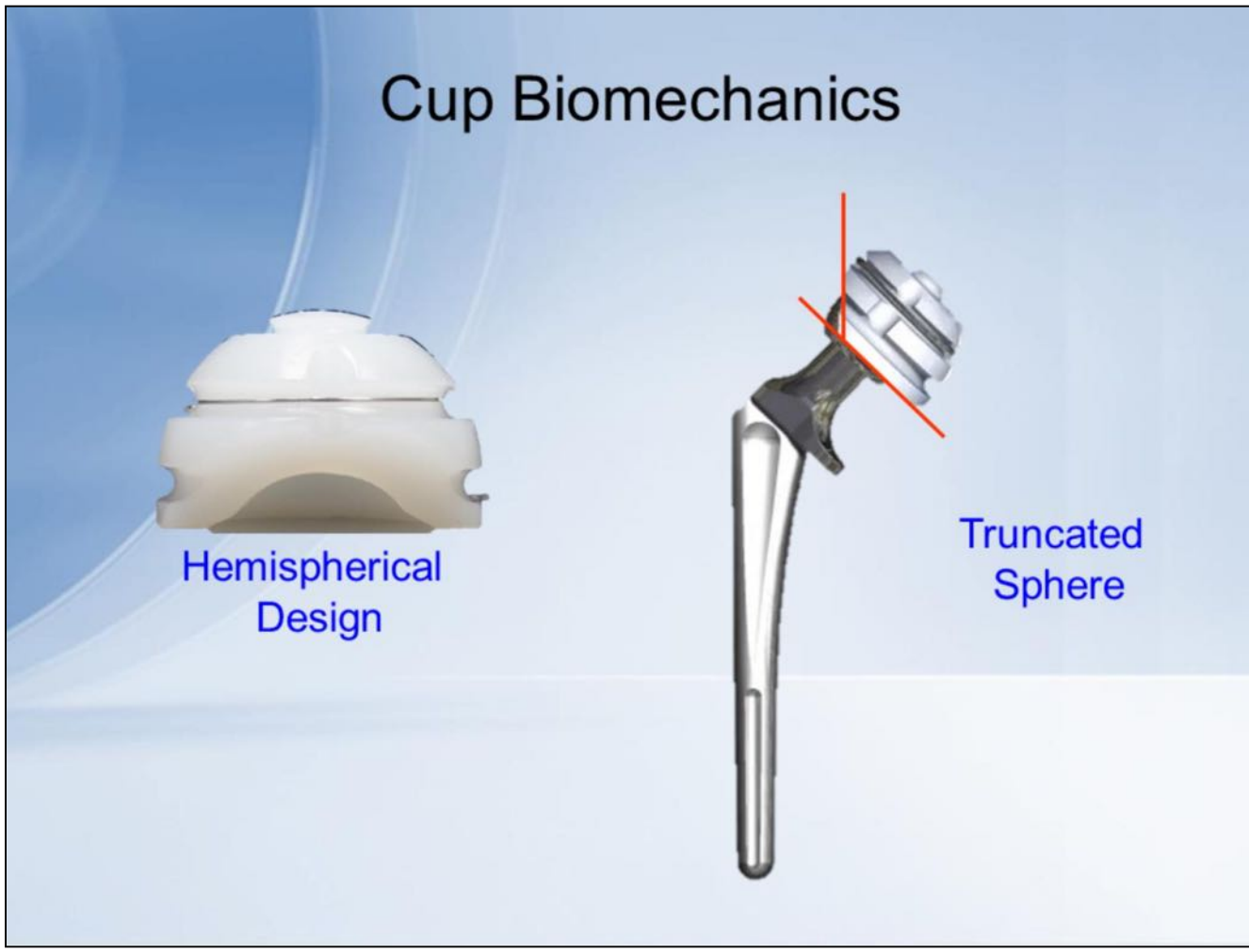
Key features of the CFX stem are similar to the BFX

Except the design addresses cement fixation

Stem is cobalt chrome

For long term success the objectives are a uniform cement mantle around the stem and

For the design to direct stresses to the mantle in compression rather than shear or tension.



The CFX cup design (as the BFX) is a truncated sphere

Truncation provides for increased abduction without luxation.

Cement fixation is accomplished through circumferential grooves for retention in the preparation and radial grooves fro torsional resistance.

BioMedtrix has veterinary bone cement which has over 15 years clinical experience in humans.

The most widely used cement in humans in Simplex bone cement mfg'd by Stryker.

This vet bone cement has similar strength properties as Simplex. Mixing and handling is slightly different with our cement having a longer liquid phase.

We will be using this in the lab on Sunday.

-Optimizing fixation with PMMA requires improved cement technique; originally cement was allowed to reach the dough state and then rolled and packed into the preparations.

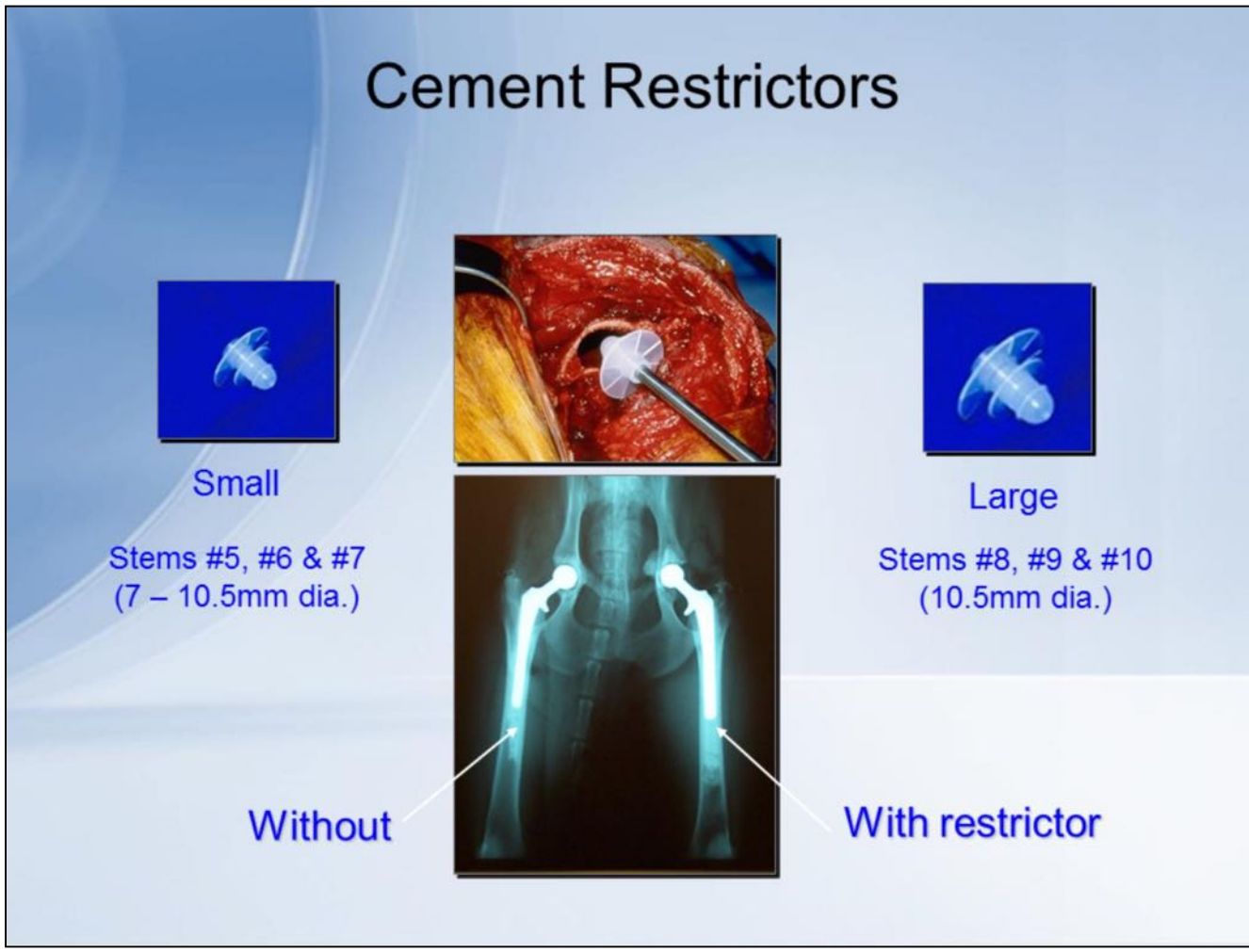
This method was not found to be consistent. So

Ancillary cement instruments and implants were developed to assure mantle integrity

This includes use of a restrictor to occlude the canal and help back fill/pressurize the cement.

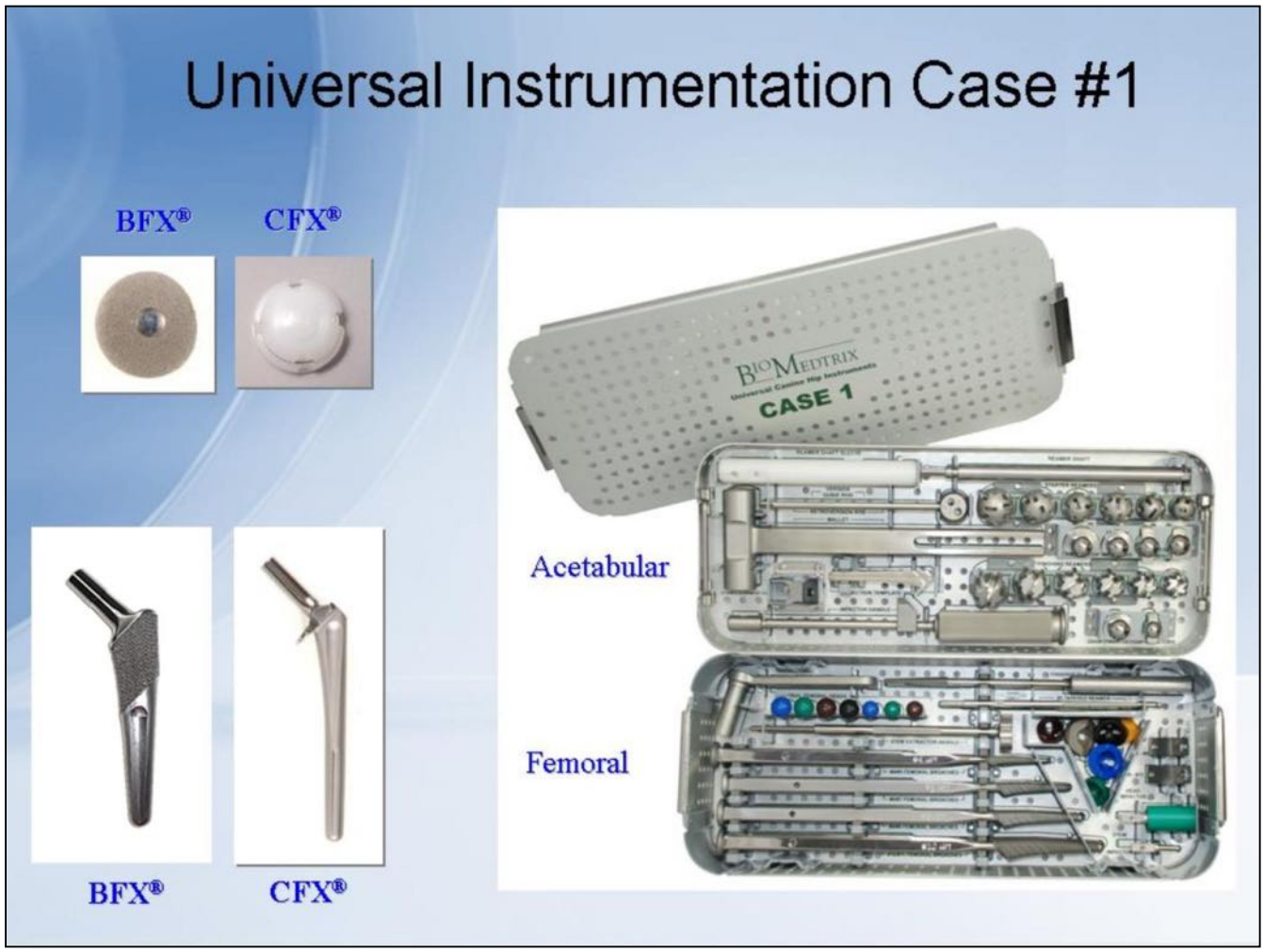
Centralizer stem tip to prevent paper thin cement mantles which can lead to mantle fracture.

Cement gun to inject the cement and properly back fill from distal to proximal.



Restrictors provide back pressure, better fill and improved cement interdigitation into the cancellous bed

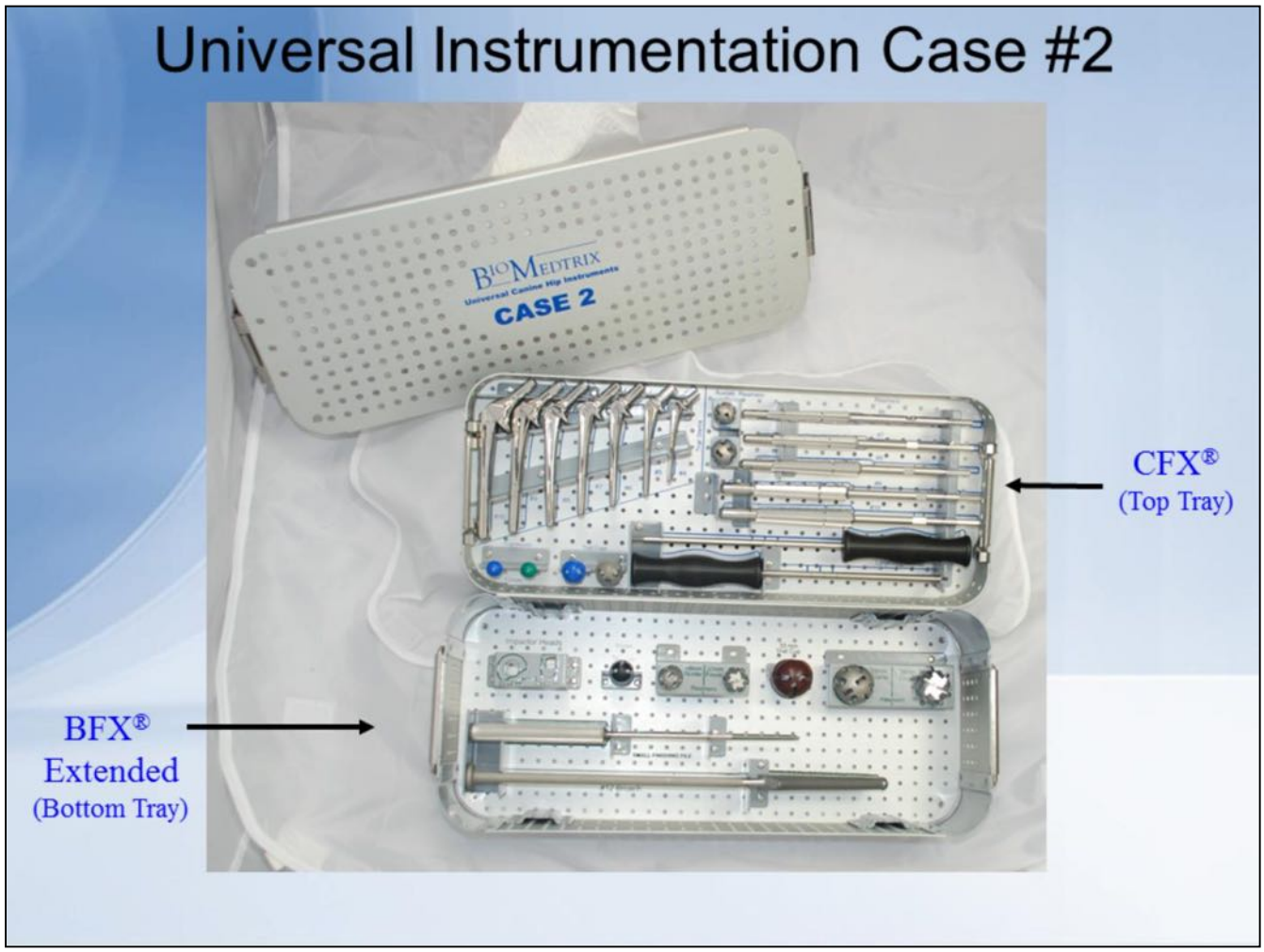
Promotes and improved cement mantle



Universal Instrument Set supports one surgical technique for both cemented and cementless systems

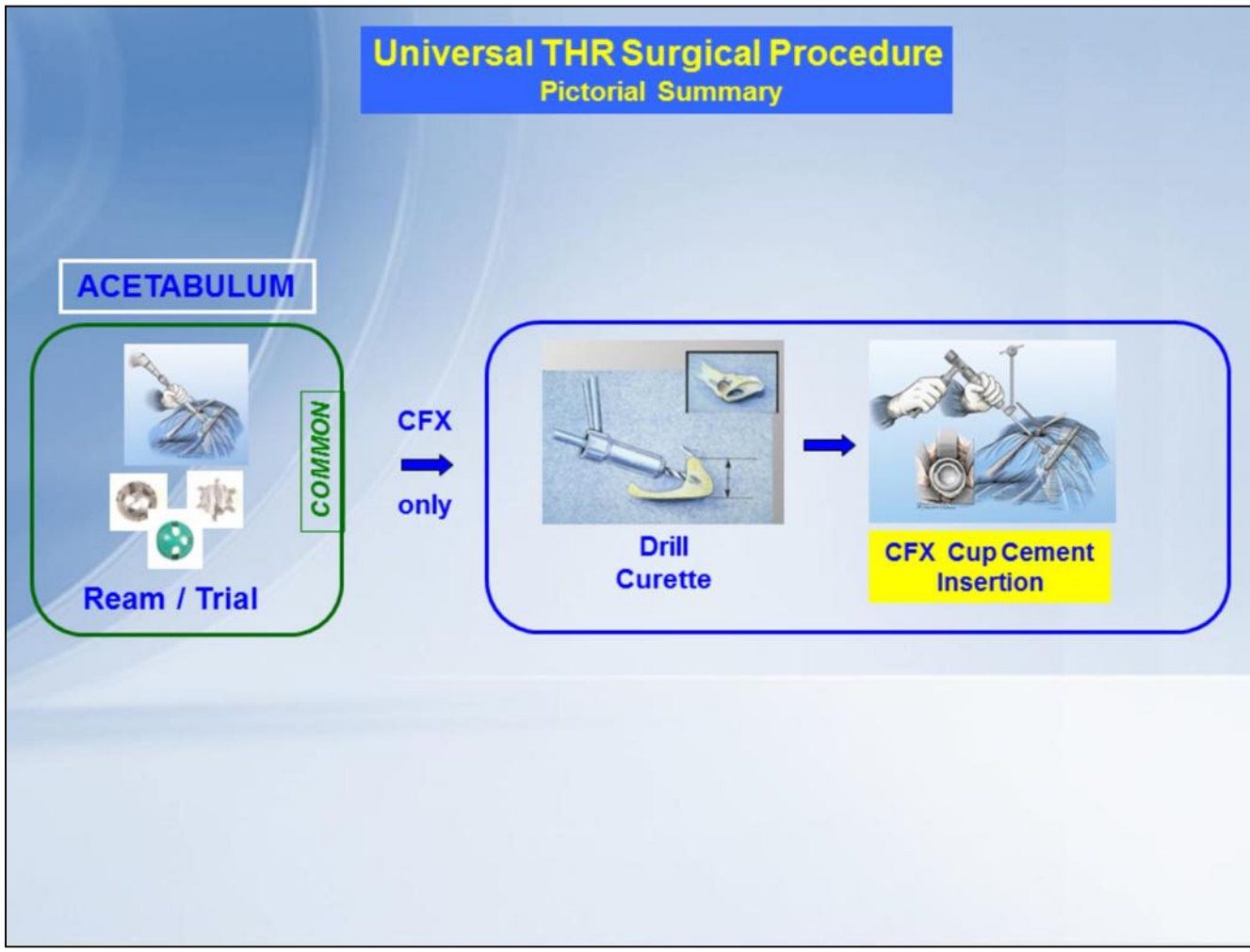
Case #1 provides both the femoral and acetabular prep's –common prep's for both systems

With the BFX System, the preparation is complete. In a cemented application, move to Case #2.



Ancillary instruments are provided to support the continued preparation for the cemented implants.

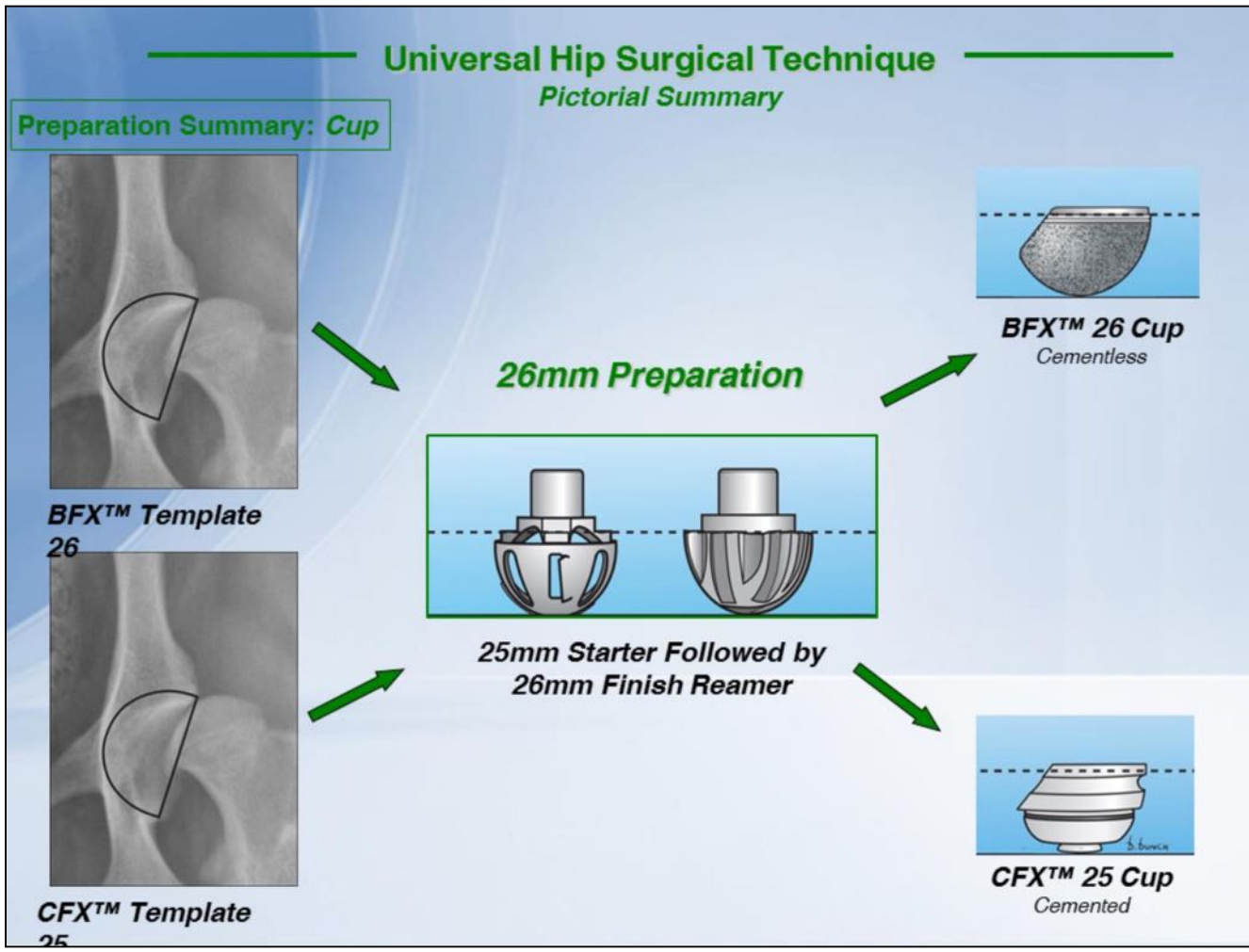
Also, the bottom tray provides extended sizes for the BFX System.



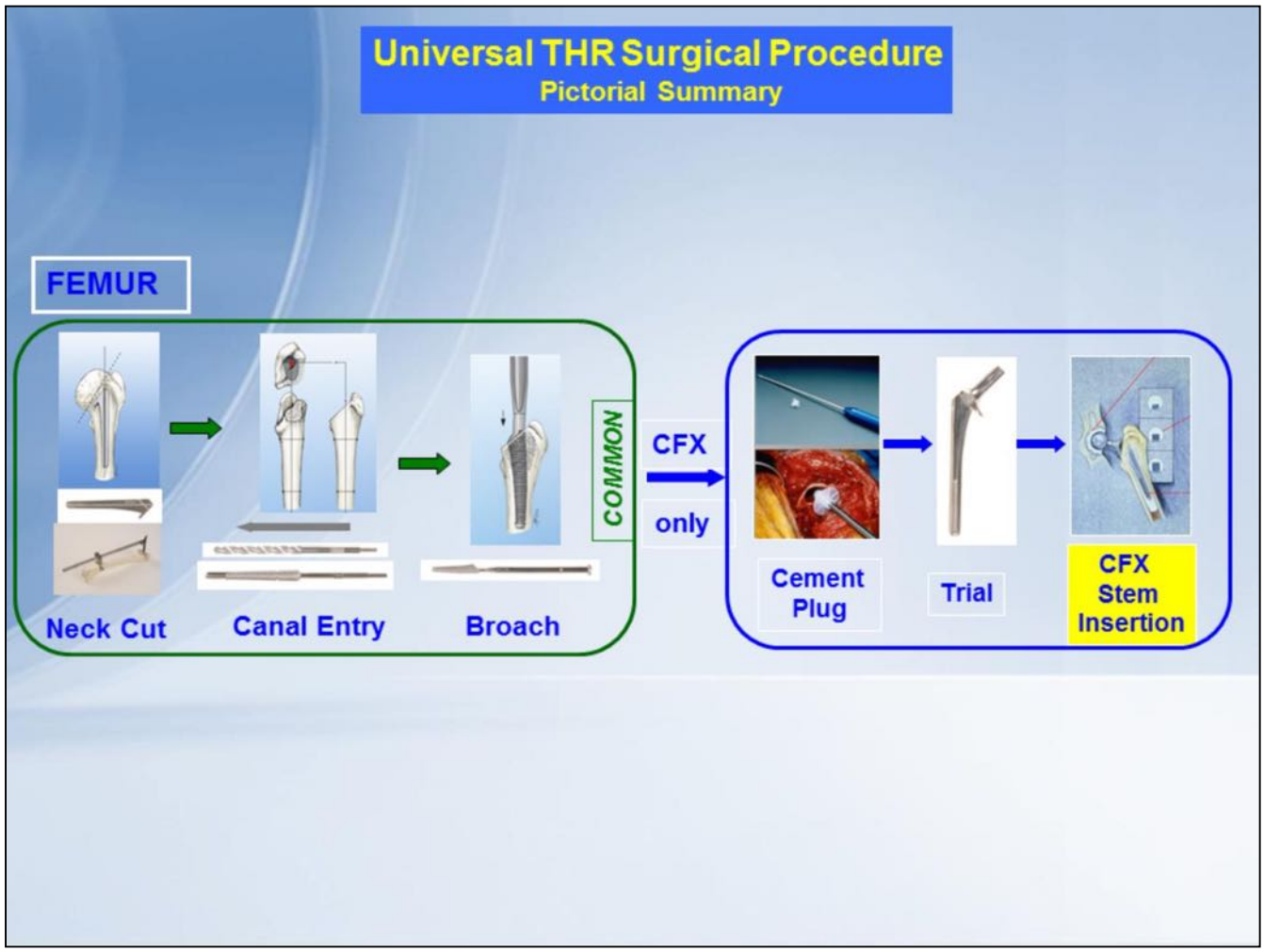
This is the technique summary

Common Acetabular preparation which provides the cementless preparation first, then can be modified to cement the CFX cup.

The if the CFX is the proper indication, the additional steps are performed for using PMMA.

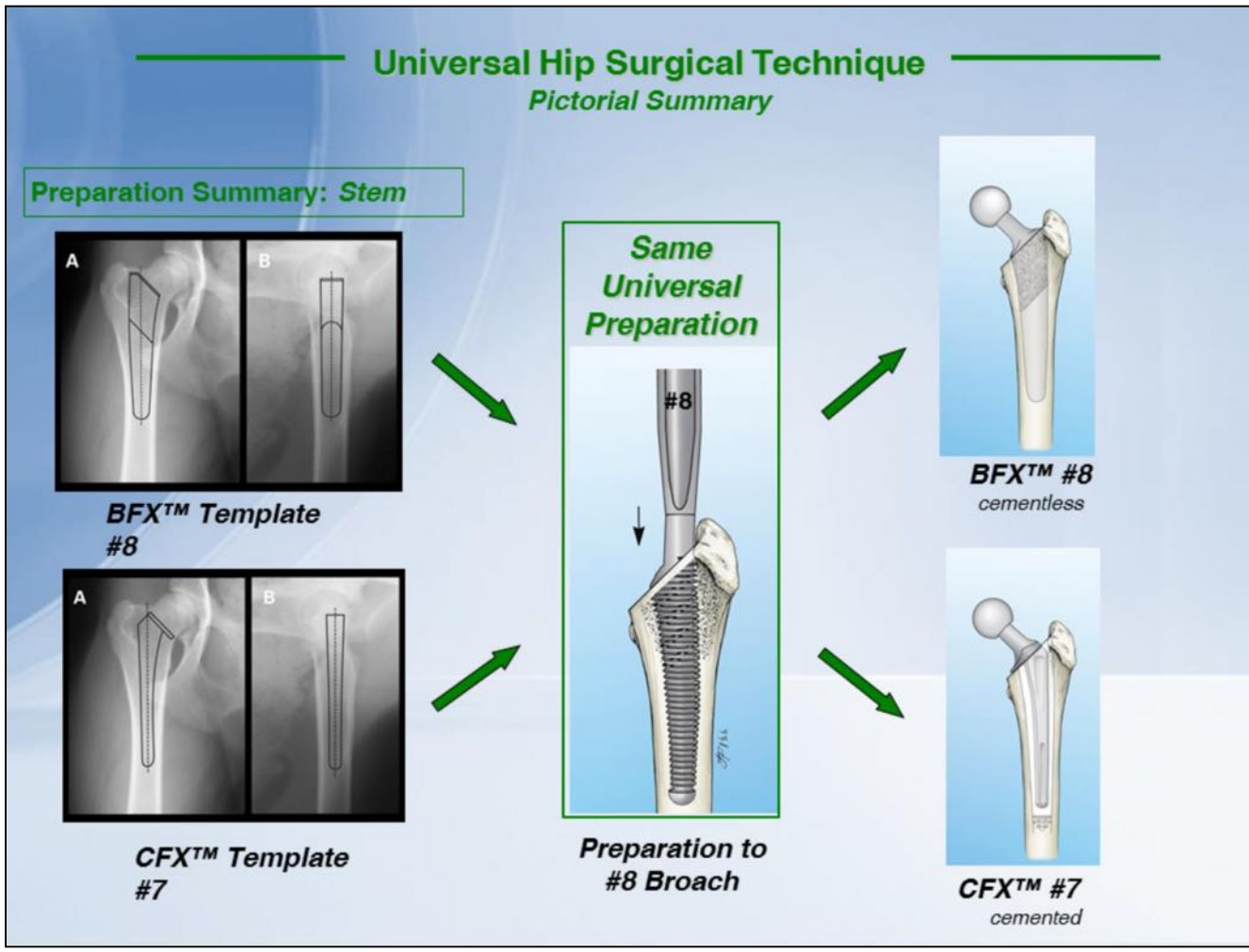


Pictorial summary of the acetabular preparation. For example, if the pre-op sizing indicates a 26mm preparation, the 25mm Starter Reamer followed by the 26mm Finishing Reamer are used. That creates a 26mm preparation. In that prep, a CFX 25mm cup can be cemented or a BFX 26mm cup can be press fit.

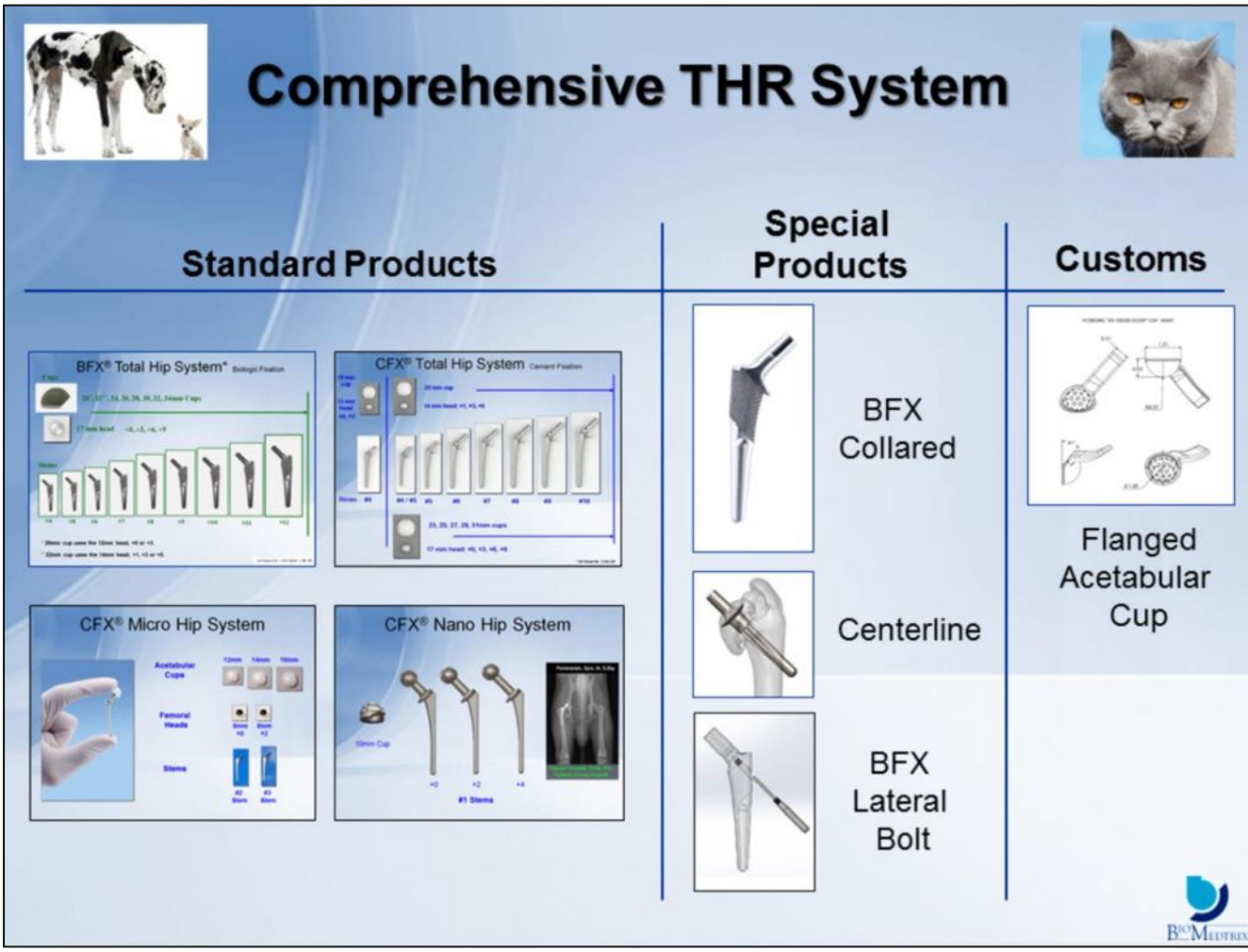


On the femoral side the concept is consistent, a common femoral preparation, first for the BFX.

The if the CFX is the proper indication, the additional steps are performed for using PMMA.



Pictorial summary of the femoral preparation. For example, if the pre-op sizing indicates a #8 preparation, the broaches are sequentially introduced until reaching the #8 Broach. After it is fully inserted, that will be a #8 preparation. In that prep, a CFX #7 stemcan be cemented or a BFX #8 stemcan be press fit.



Important that companies also support these specialty practices through implant design and availability.

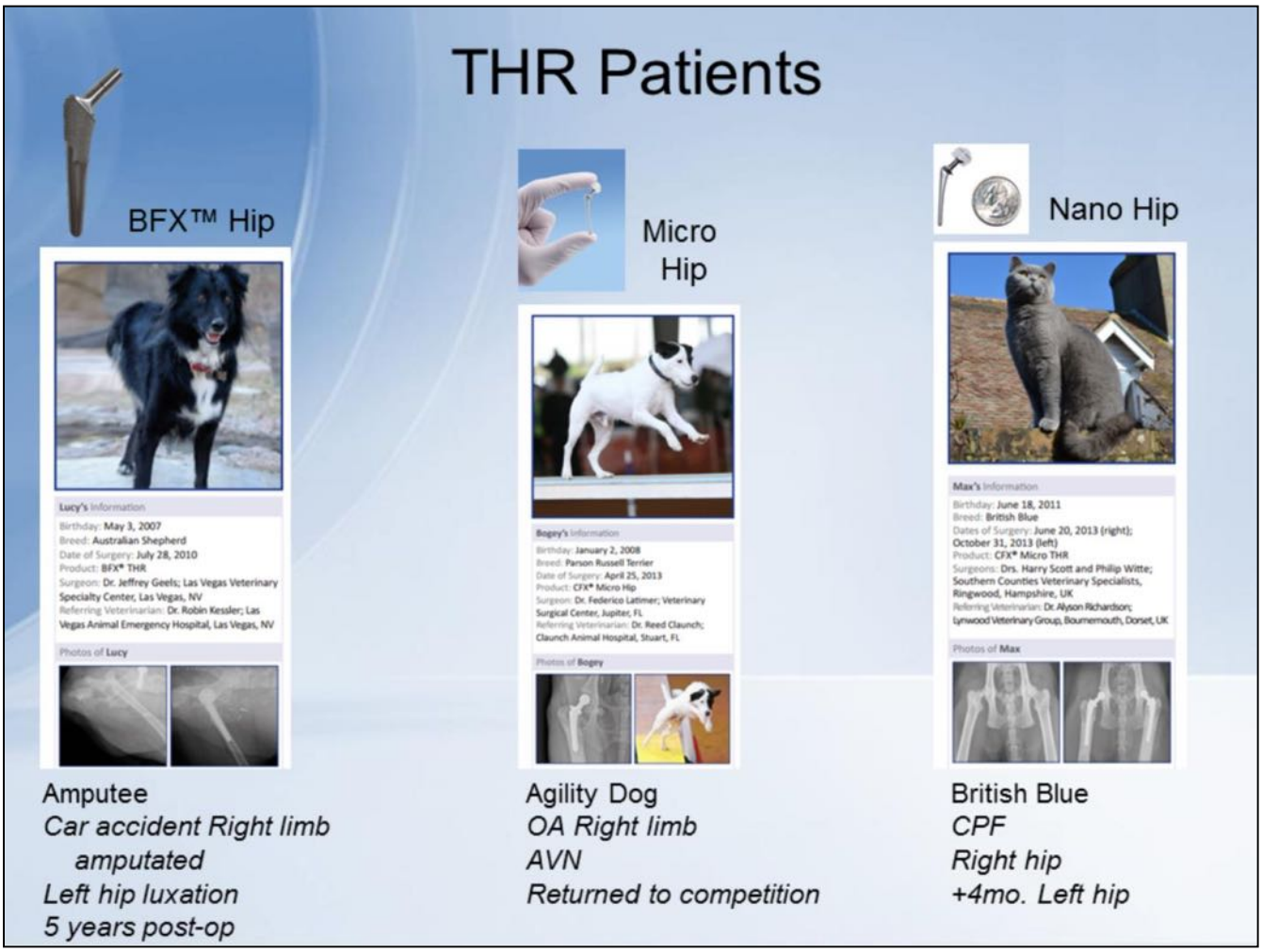
This needs a comprehensive hip system addressing diversity in patients and indications

Composed of standard product lines which address 90%= of cases.

Special products addressing the other 10% of indications and provide the design evolution of the system keeping it current

and finally customs. There are always cases which fall out of the norm through deformities or trauma which can only be meet with a custom implant.

Really not a system that can be used correctly when performing 3 or 4 cases each year. We would much prefer those cases are referred to a center of excellence doing sufficient numbers to select the appropriate implants for the patient's indications.



These are a few of our THR patients from last year.

Amputee from Nevada, Micro hip from Florida, and Nano hip from England.

Illustrates the diversity needed within a system.


THANK YOU